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In The
Supreme Court of the United States

BALDEV RAJ BHUTANI and
ALRA LABORATORIES, INC.
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

Petition for Writ of Certiorari

MARK LONDON
Counsel of Record
CHRISTOPHER B. MEAD
LONDON & MEAD
1225 19th Street, N.W.
Suite 320
Washington, D.C. 20036
(202) 331-3334

MARK L. SHAW
333 North County Street
Suite 302
Waukegan, Illinois 60085
(847) 244-4696

Counsel for Petitioners

THE LEX GROUP[DC] ◆ One Massachusetts Ave., NW ◆ Suite 670 ◆ Washington, DC 20001
(202) 789-2400 ◆ (800) 815-3791 ◆ Fax: (202) 789-1911 ◆ www.thelexgroupdc.com

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QUESTIONS PRESENTED

I. Whether the reasoning of *United States v. Neder*, 527 U.S. 1 (1999), mandates that materiality is an element of an "intent to defraud and mislead" under the Food, Drug & Cosmetic Act, particularly when the Government claims that an intent to obstruct its regulatory function is sufficient to support a felony conviction even in the absence of proof that consumers received unsafe or ineffective drugs?

II. Whether the Seventh Circuit was correct in ruling hat the intent of Congress may override the plain language of a criminal statute that, as the Seventh Circuit conceded, did not criminalize the alleged conduct by Defendants?

III. Whether the Seventh Circuit was correct in relying on a sentencing guideline cross-reference harmful to Defendants that was adopted after the offenses of conviction occurred, and in rejecting Defendant's ex post facto argument by holding that "judges must apply the Guidelines in force when a defendant is sentenced?"

IV. Whether unrebutted defense expert testimony denying an element of the offense rendered the government's evidence insufficient as a matter of law?

V. Whether the Seventh Circuit was correct in holding that violations of a regulatory scheme caused a fraud loss to consumers, even in the absence of evidence that consumers received unsafe or ineffective drugs?

VI. Whether this Court should exercise its supervisory power when the Seventh Circuit adopted demonstrably false representations from the Department of Justice that at trial "A[t]he government did not dispute that before being spiked with sodium hydroxide the old Lactulose lots were within the approved pH range, medically effective, and stable," when government counsel told the district judge during Rule 29 argument that the evidence presented to the jury proved that Alra's Lactulose was medically ineffective before the alleged addition of sodium hydroxide, Tr. 4232-3; when Counts Three and Six of the Indictment alleged that the lots were adulterated because they consisted of a "decomposed substance, namely decomposed lactulose raw material;" when Government counsel told the jury during closing argument that "Lactulose is an unstable sugar," Tr. 5612; and when Government counsel told the jury "[the Defendants] injected a chemical into the product to mask the fact that the product had degraded. Why? Because destroying the product would cost money, and selling the expired product would make money?" App. 38.

PARTIES TO THE PROCEEDINGS

Defendants Baldev Raj Bhutani, Ph.D. and Alra Laboratories, Inc. respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Seventh Circuit.

Alra Laboratories, Inc. does not have any parent companies or subsidiaries.

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OPINIONS BELOW

On December 16, 1997, district judge John F. Grady entered a 30-page Memorandum Opinion granting Defendants a new trial based on newly discovered evidence and/or violations of *Brady v. Maryland*, reprinted in the appendix hereto at 37 ("App. __"). The Seventh Circuit issued an opinion reversing the district court and remanding for reinstatement of convictions and sentencing, reported at 175 F.3d 572. App. 22. The Seventh Circuit denied rehearing, App. 21, and this Court denied certiorari. 528 U.S. 1161 (February 22, 2000). App. 20.

On remand, the district court denied Defendants' renewed motion for a new trial, holding that materiality was not an element of an "intent to defraud and mislead" under the Food, Drug & Cosmetic Act ("FD&C Act"), and noting that although the government had changed its position during appeal, the Seventh Circuit's first opinion held otherwise. App. 18.

The district court found that the government had not proved that Defendants' conduct continued past November 1, 1991. Tr. 6/16/00 at 82. It sentenced Defendant Bhutani to 30 months imprisonment, a fine and restitution, and fined Alra $125,000. The Seventh Circuit affirmed Defendants' convictions and sentence in a published opinion reported at 266 F.3d 661. App. 1. The Seventh Circuit denied Defendants' Petition for Rehearing and Suggestion for Rehearing En Banc, App. 17.

The Seventh Circuit stayed its mandate pending this petition for certiorari. App. 16.

JURISDICTION

The Seventh Circuit entered its order affirming Defendants' convictions and sentences on September 12, 2001, and denied Defendants' Petition for Rehearing and Suggestion for Rehearing En Banc on November 14, 2001. 28 U.S.C. § 1254(1) confers jurisdiction on this Court.

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED IN THE CASE

Article I, Section 8 of the United States Constitution provides, in relevant part, "No . . . ex post facto Law shall be passed." Between 1984 and 1990, 21 U.S.C. 331(e) listed prohibited acts under the Federal Food, Drug and Cosmetic Act, including violations of 21 U.S.C. 355(j). 21 U.S.C. 333(a)(2) provides, in relevant part, "if any person . . . commits such a violation [of 21 U.S.C. 331] with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined . . . ." U.S.S.G. 2N2.1 applies to "Violations of Statutes and Regulations Dealing With Any . . . Drug," Application Note 1 provides, "This guideline assumes a regulatory offense that involved knowing or reckless conduct." 2N2.1 section (b)(1), effective November 1, 1992, provides "[i]f the offense involved fraud, apply 2F1.1 (Fraud and Deceit)." U.S.S.G. 2F1.1 provides sentencing enhancements for fraud "loss."

STATEMENT OF THE CASE

After a ten-week trial, the jury convicted Dr. Baldev Raj Bhutani, his wife Neelam Bhutani, and Alra Laboratories, Incorporated ("Alra") of conspiracy and various violations of the Federal Food, Drug and Cosmetic Act ("FD&C Act"). The trial court had jurisdiction because Defendants were charged with violating federal criminal statutes. Dr. Bhutani, a U.S. citizen, is the President and majority owner of Alra, a generic drug manufacturer.

Count Four of the Superseding Indictment, and certain overt acts of the conspiracy alleged in Count One, charged Defendants with a failure to establish and maintain accurate drug manufacturing batch production records in 1988-89, in violation of 21 U.S.C. 331(e), which lists a number of prohibited acts under the FD&C Act. Because of a drafting error in a statutory amendment, a failure to establish and maintain

accurate batch production records was not one of the listed prohibited acts under 21 U.S.C. 331(e) between 1984 and 1990. The district court and the Seventh Circuit conceded that under the literal language of the FD&C Act, there were no criminal penalties for failing to keep accurate batch records during the relevant time period, but upheld Defendants' convictions because they opined that Congress did not intend to repeal criminal penalties for inaccurate batch production records.

The counts of conviction related to three separate episodes at Alra's generic drug manufacturing plant. First, part of Count One (a conspiracy count) and Counts Three, Four, and Six alleged that, in August 1988, Alra employees added sodium hydroxide to decomposed Lactulose Syrup to mask degradation of the drug product.

Second, the conspiracy count and Counts Seven and Eight alleged that in September 1989, Alra manufactured different lots of Lactulose Syrup using raw material, Lactulose Concentrate, that had arrived in leaking drums, allegedly exposing the raw material to a "possibility" of contamination.

Third, the conspiracy count and Count Ten alleged that in 1989, a stainless steel pipe accidentally fell into a mill during Alra's manufacture of a different generic drug product, K+10 (potassium chloride), causing the lot to be contaminated with metal shavings.

Addition of Sodium Hydroxide

Key allegations in the Superseding Indictment (Overt Acts 2 - 7 in Count One, and Counts Three, Four, and Six) related to Alra's manufacture of lots 52-230-P and 52-231-P of Lactulose Syrup, USP ("the two lots"). Lactulose Syrup is a liquid prescription laxative used to treat liver disease by removing ammonia that builds up in the colon. The government's theory was that Defendants added sodium hydroxide in an unauthorized manner to the two lots to conceal their "degradation" and "decomposition."

Alra filed an Abbreviated New Drug Application ("ANDA") in May 1986, seeking U.S. Food and Drug Administration ("FDA") approval to market a generic version of Lactulose Syrup. Tr. 187, 241. The simple manufacturing process approved in Alra's ANDA called for adding dye and purified water to Lactulose Concentrate, and then adjusting the pH (the acidity) of the solution by adding any amount between 20 and 2,000 grams of sodium hydroxide. Tr. 244-45, 279. Because Lactulose Syrup is a liquid product readily absorbed into the colon, FDA did not require Alra to prove that its Lactulose was bioequivalent to the name brand drug, and the bioequivalence of Alra's Lactulose was never in dispute during the trial.

Alra first mixed and bottled the two lots in June 1986. FDA approved Alra's ANDA for Lactulose Syrup in July 1988. Tr. 339. Alra's Quality Control laboratory tested samples from the two lots in early August 1988. Each lot assayed at 100% of label claim for the active ingredient, and the pH values for the two lots ranged from 5.3 - 5.6, well within the approved pH range for Lactulose Syrup of 3.0 - 7.0. Tr. 5000-03.

The disputed portion of the government's evidence included testimony that, a week after Alra obtained these passing lab results, a team of Alra employees unpacked the two lots from storage crates, opened each of 3,365 bottles from the two lots, added sodium hydroxide from a steel bucket bottle-by-bottle with some sort of turkey baster or syringe , shook the bottles, recapped the bottles, labeled them, and repacked them in crates. This process would technically violate the FD&C Act because Alra's approved manufacturing process required that sodium hydroxide be added in a mixing vat and because employees failed to document the addition of sodium hydroxide.

Batch records and time records showed that seven Alra employees had packaged the two lots on August 11-12, 1988. Tr. 1200-01, 1209-10. Four of those seven employees testified for the government; three testified for the defense. None of the government's witnesses was asked about the incident until

three years after it occurred; none had believed there was anything illegal about the process when it happened; none knew what substance had been added; one witness said it was possible something was being removed from the bottles; two witnesses said they were not sure something was added to every bottle. Tr. 1385, 1421-3, 1431, 1520, 1525, 1530, 1818-21, 3236, 3247, 3255, 3261.

The Bhutanis testified that there was no reason to adjust the pH of the two lots, because the lots readily passed lab testing in early August 1988. Tr. 5000-04, 5250. The defense contended that the employees had been replacing leaking caps and adding additional Lactulose to under-filled bottles. The batch records for the two lots demonstrated that some of the caps on the bottles had been replaced because they were leaking.

The government's evidence on this episode was weak and controverted. The district judge felt the verdict could have gone "either way:"

> The description of the injection process given by the various employees who allegedly did it seemed unlikely in the extreme, unless there was some compelling motive for the defendants to have required them to engage in such a procedure. Not all of the employees who would have known about the incident agreed that it had occurred. Both of the Bhutanis denied that it had occurred. It seemed to the court at the time that the verdict could have gone either way, and, of course, there is no way of knowing how close the jury thought the question was. One thing that can be said for certain is that if the jury had entertained a reasonable doubt as to whether the defendants had a plausible motive for engaging in what otherwise would have been bizarre behavior, it could not have found the defendants guilty on Counts 3, 4 and 6.

App. 65.

The government had no direct proof of the Defendants' motives for supposedly adding sodium hydroxide to the two lots in 1988. No one testified that the Bhutanis said that they wanted to raise the pH of the lots to conceal the age or degradation of the lots. None of Alra's customers testified, and there was no evidence that Alra's customers would have discerned the age or degradation of the lots from slight variations in pH values.

Nevertheless, the government made an emotional jury argument that Defendants had greedily sold "degraded" and "expired" Lactulose without regard for public health, in order to persuade the jury that Defendants had an "intent to defraud or mislead" for an otherwise minor regulatory violation. Counts Three and Six of the Indictment alleged that the two lots were already adulterated on the date of the alleged addition of sodium hydroxide because they consisted of a "decomposed substance, namely decomposed lactulose raw material." Government counsel told the district court three days before trial that "the government's theory of the case" was that the Lactulose Syrup was "no longer stable" before the sodium hydroxide was added. Tr. 12/4/95 at 5. Government counsel told the district judge during Rule 29 argument that the evidence presented to the jury proved that Alra's Lactulose was medically ineffective before the alleged addition of sodium hydroxide. Tr. 4232-3. Government counsel told the jury during closing argument that "Lactulose is an unstable sugar." Tr. 5612. Government counsel told the jury "[the Defendants] injected a chemical into the product to mask the fact that the product had degraded. Why? Because destroying the product would cost money, and selling the expired product would make money." App. 40.

As the district court's opinion granting Defendants' new trial motion summarized, government counsel, at trial, argued that the two lots were

> old and had become unstable or dangerously close to being unstable, so that they were either medically ineffective or close to becoming

> medically ineffective. It was for this reason, according to the government, that defendants injected these aged Lactulose lots with Sodium Hydroxide, a base, in order to raise the pH of the Lactulose and make it appear safe for use. . . . The motive was profit, said the government.

App. 39.

After post-trial Brady discovery revealed that voluminous data in FDA's files contradicted the prosecution's theory that a decline in pH correlated to a decline in medical effectiveness in Lactulose Syrup, the government abruptly changed its position. The government told the Seventh Circuit that at trial it "did not dispute that before being spiked with sodium hydroxide [the two lots] were within the pH range, medically effective, and stable." Government's Reply Brief at 6.

Leaking Drums of Lactulose Concentrate

Alra bought its Lactulose Concentrate from a Japanese manufacturer that shipped the product in 55-gallon steel drums in a dedicated, but not air tight, sea container. The drums in one shipment rubbed against each other during "rough seas," and sprung leaks. Defendants used the shipment after testing each drum for microbial and physical contamination, following the test procedures required by the FDA. Lactulose is not a sterile product.

During an inspection within weeks after the leaking drums arrived, an FDA inspector confirmed in a conversation with Dr. Bhutani that Defendants had used the leaking drums. The FDA inspector did not even note the use of the leaking drums as a regulatory violation, and took no steps to initiate a recall or take any other regulatory action. Five years later, the grand jury indicted Defendants, alleging in Counts Seven and Eight that use of the leaking drums violated the FD&C Act because the product was subject to a "reasonable possibility of

contamination." There were no consumer complaints that these batches were ineffective or contaminated.

The Defense called John R. Robyt, a Professor of Biochemistry for 31 years, as an expert in the field of carbohydrate chemistry. Tr. 4256-62. The government's own carbohydrate expert acknowledged that Robyt was a well-known carbohydrate chemist whose opinion the government's expert respected. Tr. 1640. Presented with a hypothetical that accurately described the transport of the leaking drums, Dr. Robyt testified that the leaks in the 55-gallon drums did not present any danger to the Lactulose. He explained that Lactulose is a thick, sugary syrup with high osmotic pressure that would not support the growth of microorganisms and would not absorb organic volatiles. Tr. 4287-90.

Over repeated defense objections, the government called two CGMP "experts," Anthony Lord and Garnet Edward Peck, to testify about FDA's ambiguous regulations for receiving raw materials, and the rationale behind those regulations. Both Lord and Peck speculated that unspecified airborne organic volatile impurities ("OVIs") or pesticides could have somehow wafted into the leaks in the drums, or that mold or yeast could have grown in the product. But Lord and Peck knew nothing about Lactulose chemical properties, and could not say that OVIs or pesticides got within 100 miles of the drums. Tr. 630-31, 708, 724, 3373-79, 3316-18. They offered no testimony that the product was "injurious to health." The Indictment charged the possibility of "microbial" contamination, but OVIS are not microbial. The government's speculative "expert" testimony simply inflamed the jury.

The Pipe Accident in a Lot of K+10

It was undisputed that a steel pipe slipped into a Fitz Mill during Alra's manufacture of a lot of K+10 (Potassium Chloride) tablets. Count Ten of the Superseding Indictment alleged that the lot was contaminated with metal shavings. An ex-employee testified that Dr. Bhutani had ordered the

destruction of the drum of product that had been under the Fitz Mill when the accident occurred. Tr. 5181. The same two disgruntled employees who were the government's key witnesses on the alleged addition of sodium hydroxide to the two lots of Lactulose Syrup testified that the Bhutanis instructed them to sift the entire batch with magnets to remove metal, and that the product was shipped despite the two employees' belief that they had not succeeded in removing all the metal. Again, there were no consumer complaints of metal in that lot, and FDA's extensive lab testing of Alra's products failed to find any metal contamination.

Materiality

Defendants vigorously challenged the materiality of the alleged FD&C Act violations. On the incident involving the alleged addition of sodium hydroxide to the two lots, Defendants argued that the allegedly "degraded" Lactulose was stable as a rock, that sodium hydroxide was an approved ingredient in Alra's formulation, and pointed to an absence of consumer complaints. On the incident involving the use of leaking drums, Defendants introduced unrebutted expert testimony from a distinguished professor of biochemistry that the osmotic pressure and chemical characteristics of Lactulose would prevent the kinds of contamination alleged by the government, and that an FDA inspector had known about the use of the leaking drums, but taken no regulatory action. On the incident involving the K+10 pipe accident, Defendants pointed out that the government's witnesses testified that they tried to get all the metal contamination out of the batch; that at a meeting with Alra's counsel, FDA representatives had not disputed that using magnets to remove metal contamination was an accepted industry practice; that testing laboratories, including FDA's own, had searched for metal in Alra's products and found none; and Defendants again pointed to an absence of consumer complaints.

The district court denied Defendants' request for a jury instruction to the effect that materiality was an element of FD&C Act violations. Defendants' request occurred in the context of the record keeping prong of the conspiracy count, but its theory applied equally to all counts of conviction. Tr. 5863. The district court also refused a requested instruction to specify the manner in which Defendants allegedly violated the FD&C Act in connection with Count Ten of the Indictment. Tr. 5866-67, 5867.

The District Court Granted a New Trial

After trial, a publication of the United States Pharmacopoeia suggested that FDA had been in possession of data showing that there was no correlation between a decline in the pH of Lactulose and its medical effectiveness. The district court ordered post-trial discovery over the government's objection. In a 30-page Memorandum Opinion that quoted extensively from the government's arguments to the jury and its questions to expert witnesses, the district court found that Lactulose stability data in FDA's files contradicted the government's theory that Defendants had added sodium hydroxide to Lactulose lots to raise their pH and thus conceal their "degradation." Explicitly finding that the stability data in FDA's files "seriously undermines the court's confidence in the verdicts," the district court granted Defendants' motion for a new trial. App. 37-68.

The Seventh Circuit Adopted the Government's Misrepresentations

The government appealed, and claimed that at trial it "did not dispute that before being spiked with sodium hydroxide [lots 52-230 and 52-231] were within the pH range, medically effective, and stable." Government's Reply Brief at 6. The government's statement that it conceded all along that the lots were medically effective and stable is utterly,

demonstrably false. Nonetheless, the Seventh Circuit reversed, adopting the government's misrepresentations that "the government did not argue that the Lactulose was unfit, or close to unfit." 175 F.3d at 578, App. 31-32

The District Court Denied Defendants' Renewed New Trial Motion on Remand

After remand, Defendants filed a renewed motion for a new trial, contending that if the jury had heard the government's admissions during appeal that the Lactulose was medically effective and stable before the alleged addition of sodium hydroxide, the outcome of the trial would have been different. The district court denied the motion. The district court agreed that the government had changed its position on appeal, and that the government had argued at trial that "the lactulose had decomposed to the point of ineffectiveness." However, the district court read the Seventh Circuit's opinion as precluding it from considering the factual premise of Defendants' motion. App. 18-19. In granting bail pending appeal, the district court said, "if the defendants do get the attention of the Court of Appeals, there is a good likelihood that a new trial will result. . . ." Tr. 2/15/00 at 121-22.

The district court also rejected Defendants' motion for a new trial based on its failure to grant a jury instruction that materiality was an element of felony violations under the FD&C Act. The district court held, "We agree with the government that [*United States v.*] Neder's materiality requirement does not apply to the statutes involved in this case." App. 19.

Sentencing After Remand

The district court refused to sentence Defendants under U.S.S.G. 2N2.1 ("Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, or Agricultural Product"), and instead sentenced

them under U.S.S.G. 2F1.1 ("Fraud and Deceit"). However, the district court found that the government had failed to prove, during trial or sentencing, that the offenses of conviction had rendered Alra's drugs unsafe or ineffective:

> Taking the counts one by one, there is no evidence that Dr. Bhutani regarded the injection of Lactulose into the individual bottles with syringes as creating a risk of serious bodily harm to people who might use the Lactulose Syrup. What was being injected was sodium hydroxide, which was something that was normally added to the drug. What occurred here was that it was added in a different manner than authorized by regulations, and the addition in that manner was not documented. . . .
>
> The government had itself changed its position as to what the risk was at least three times during the course of this litigation. It told the jury at trial that the risk was in the Lactulose itself in that it had degraded or decomposed to the point where it was no longer medically effective and that the injections of the sodium hydroxide were made to mask or conceal that fact. . . .
>
> When the case went up on appeal, the government look a different position . . . .
>
> [As to counts Seven and Eight] There is no evidence whatever that the Lactulose that was used from the leaking drums had anything medically dangerous about it or that it would cause anybody any injury. There was no evidence of any actual contamination. The jury found the defendants guilty on the proposition that the reasonable possibility of contamination would be sufficient, but the reasonable possibility of contamination and the risk of serious physical injury are two very different things.
>
> People eat contaminated food every day of their lives. There is nobody in this room who won't eat some

> before the day is out. Our bodies are amazingly capable of warding off ill effects from contamination. And there is no evidence at all in this record that anything about these leaking drums was in fact dangerous to anybody. . . .
>
> Now we come to the K+10 tablets. There is no evidence that anyone was likely to be hurt from these tiny metal fragments that were in some of the pills. As the government concedes, we don't know how small the fragments were. They were certainly tiny. And there is no evidence that they presented a risk of serious, and I [underscore] the word "serious" bodily injury, or that Dr. Bhutani was conscious of such a serious risk.

Tr. 1/24/00 at 39-41.

Despite finding that the government had not proved that customers received unsafe or ineffective generic drugs from Alra, the district court found a "fraud loss" in the amount of Alra's gross sales for the lots of conviction, on the theory that consumers with perfect information would not have selected Alra's products. The district court admitted that there was no evidence in the record to support this finding: "I mean when I say that people were sold something that was different from what they felt they were getting, obviously, we have not conducted any evidentiary hearing to determine what was in the minds of people who bought these drugs. . . . We are more or less making that statement as a proposition of law." Tr. 6/14/00 at 89-90.

This "loss" enhancement increased Defendant Bhutani's offense level and resulted in a 30 month sentence, which the district court believed was "unfortunate. I think a lesser sentence would be appropriate, but I can't do anything about it." Id. at 93.

The Seventh Circuit's Second Opinion

The Seventh Circuit affirmed Defendants' convictions and sentences. App. 1-15. Without addressing the text of the Indictment, government counsel's Rule 29 argument, or the district court's extensive quotations from the trial record, the same panel that had previously adopted the government's mischaracterization of the trial arguments wrote that "[a] second read of the [5,800 page] trial transcript reveals that the government's position at trial and on appeal has been consistent." App. 2-3 Noting a split of authority, the panel upheld Defendants' convictions on Count Four and the conspiracy count "because strictly reading and applying the FDCA as it was at the time of the offense in question would put the plain language at odds with the statute's purpose and intent." App. 9.

The panel upheld the district court's decision to apply U.S.S.G. 2F1.1, relying on the cross reference in 2N2.1(b)("If the offense involved fraud, apply section 2F1.1 (Fraud and Deceit)"), and rejecting Defendants' ex post facto argument that the Sentencing Commission had not adopted the cross reference until November 1, 1992, after the crimes of conviction occurred. The panel held that "judges must apply the Guidelines in force when a defendant is sentenced." App. 11 (citation omitted).

The panel also upheld the district court's finding of fraud loss, disagreeing with the Fourth Circuit's holding in *United States v. Chatterji*, 46 F.3d 1336 (4th Cir. 1995), and declining to apply *United States v. Maurello*, 76 F.3d 1304 (3d Cir. 1996) by analogy. The panel wrote: "[t]he medical effectiveness of the drug or its dangerousness after adulteration ought not to be the core of the inquiry; . . . there was indeed loss to consumers because consumers bought drugs under the false belief that they were in full compliance with the law." App. 11-14.

The panel's opinion did not even address Defendants' arguments that the district court should have instructed the jury that materiality was an element of an "intent to defraud

and mislead" under the FD&C Act, that the district court should have specified to the jury how Defendants allegedly violated the FD&C Act, and that uncontradicted defense expert testimony from a professor of carbohydrate chemistry precluded the possibility of a "reasonable possibility of contamination" under Counts Seven and Eight. The panel held "[t]he other arguments of the defendants are equally without merit and we shall not address them further." App. 15

REASONS FOR GRANTING THE WRIT

The Seventh Circuit stayed issuance of its mandate pending Defendants' petition for certiorari without opinion, suggesting that it believed this case presents important issues. App. 17

The district court's refusal to instruct the jury that materiality was an element of an "intent to defraud and mislead" under the FD&C Act conflicted with a relevant decision of this Court, *United States v. Neder*, 527 U.S. 1 (1999), on an important question concerning the enforcement of an exceptionally broad regulatory statute where the circuit courts have found that an "intent to defraud" the FDA, rather than an intent to defraud consumers, is sufficient to support conviction. The district court's opinion is further evidence of a split in the circuits on this important federal question. The Ninth Circuit recently held that materiality was an element of felony violations under the FD&C Act, while the Eighth Circuit held that an analogous provision in the Federal Meat Inspection Act did not require a showing of materiality. Compare *United States v. Watkins*, 2002 U.S. App. Lexis 1197 (9th Cir., January 29, 2002) with *United States v. Jorgensen*, 144 F.3d 550 (8th Cir. 1998).

The Seventh Circuit's opinion that the intent of Congress may override the plain language of a criminal statute explicitly noted a conflict in the circuits on this important federal question.

The panel's rejection of Defendants' ex post facto argument, and its holding that "judges must apply the Guidelines in force when a defendant is sentenced," conflicts with relevant precedent of this Court and the uniform precedent of the circuit courts of appeal on an important federal question.

The panel's affirmance conflicts with precedents from other circuits holding that unrebutted expert testimony denying an element of the offense renders the government's evidence insufficient as a matter of law.

The Seventh Circuit's opinion that violations of a regulatory scheme cause a fraud loss to consumers, even in the absence of any proof that consumers received ineffective or unsafe drugs, conflicts with approaches of other circuit courts of appeals in determining fraud loss under 2F1.1.

As a result of demonstrably inaccurate government arguments that "[t]he government did not dispute that before being spiked with sodium hydroxide the old Lactulose lots were within the approved pH range, medically effective, and stable," the Seventh Circuit ignored the district court's factual finding, based on careful quotations from the trial record, that "[t]he government's contention at trial was that defendants' Lactulose lots in question were old and had become unstable or dangerously close to being unstable, so that they were either medically ineffective or close to becoming medically ineffective." App. 39. The Seventh Circuit's refusal to grant a new trial based on the government's change of position on appeal resulted in an opinion that "so far departed from the accepted and usual course of judicial proceedings . . . as to call for an exercise of this Court's supervisory power." S. Ct. Rule 10.

ARGUMENT

I. THIS CASE PRESENTS A CRUCIAL QUESTION ABOUT THE APPLICATION OF THIS COURT'S DECISION IN *UNITED STATES V. NEDER* TO THE FELONY PROVISIONS OF THE FD&C ACT.

In *United States v. Neder*, 527 U.S. 1 (1999), this Court held that when Congress used the term "to defraud" in the mail and wire fraud statutes, Congress necessarily incorporated the common law requirement of materiality as an element of the offense. Indeed, this Court held that the "common law could not have conceived of 'fraud' without materiality." 527 U.S. at 22. Every offense of conviction in this case alleged an "intent to defraud or mislead." Congress used the same common law term "to defraud" in the Food, Drug & Cosmetic Act (FD&C Act) that it used in the mail and wire fraud statutes. Neder is thus directly on point, and required the jury to find an element of materiality in FD&C Act offenses.

On January 29, 2002, the Ninth Circuit issued an opinion carefully analyzing the impact of this Court's Neder opinion on the felony provisions of the FD&C Act. *United States v. Watkins*, 2002 U.S. App. Lexis 1197 (9th Cir., January 29, 2002). Rejecting the government's argument that a materiality requirement would frustrate the public welfare purposes of the FD&C Act, the Ninth Circuit wrote:

> This argument ignores the broad reach of the statute. The misdemeanor provision, section 333(a)(1), covers a wide range of conduct, imposing strict liability . . . . The increased penalties provided by section 333(a)(2) require an additional showing of an "intent to defraud or mislead," indicating Congress' intent to limit the scope of felony liability. Considering the broad applicability of the misdemeanor . . . provision and Congress's intent to limit liability for increased penalties, requiring proof of materiality would not frustrate Congress's purpose in enacting these

> provisions of the [FD&C Act] to protect public health and safety.

2002 U.S. App. Lexis 1197 at 10-11.

Following the reasoning of this Court's Neder opinion, the Ninth Circuit held that an "intent to defraud" necessarily incorporates the common law requirement of materiality:

> because Congress expressly required proof of an "intent to defraud" for felony liability, "we cannot infer from the absence of an express reference to materiality that Congress intended to drop that element from [section 333(a)(2)]." On the contrary, "we must presume that Congress intended to incorporate materiality unless the statute otherwise indicates." Neder, 527 U.S. at 23 (internal quotations and citations omitted)(emphasis in original). The [FD&C Act's] broad coverage . . . does not otherwise dictate.

2002 U.S. App. Lexis 1197 at 11-12.

The Ninth Circuit separately analyzed "intent . . . to mislead" under the FD&C Act. Looking to the plain meaning of that phrase, the Ninth Circuit held that an "intent to mislead" also requires materiality:

> To mislead is "to lead in a wrong direction or into a mistaken belief: deceive." WEBSTER'S NEW INTERNATIONAL DICTIONARY 1444 (3d ed. 1963). In turn, to deceive is "to take unawares esp. by craft or trickery . . . to cause to believe the false." Id. at 584. Both these definitions presume an effect on another party. This understanding is reinforced by the transitive nature of the verb "to mislead." Its action requires an object-in this case another party. The addition of the word "intent" underscores the relationship between the actor and the other party. Any intent to mislead presumes an expectation or purpose that another will in fact be misled.
>
> The government would have us believe that an intent to mislead is established by showing mere knowledge of a statement's falsity by its maker. To begin as a

> matter of plain meaning, an "intent" to have knowledge of a statement's falsity makes little sense. Likewise, when we consider the government's proffered meaning, its reading is at once too narrow and too broad. . . . Simply put, knowledge of falsity places a top-sided focus on the actor and does not adequately encompass the effect of the intended action on the other party.

2002 U.S. App. Lexis 1197 at 13-14.

Defendants vigorously contested the materiality of the alleged violations at trial, and requested an instruction that materiality was an element of a failure to maintain records under the FD&C Act. Tr. 5863. Without the benefit of the Neder decision, the district court denied that requested instruction, and denied Defendants' renewed motion for a new trial, finding that materiality was not an element of felony violations of the FD&C Act. App. 18; Tr. 5868. Coupled with the district court's refusal to specify the manner in which Defendants were alleged to have violated the FD&C Act in Count Ten, Tr. 5866-67, 5867, the jury instructions severely prejudiced Defendants.

There is a split in the circuits on this issue. The district court's opinion in this case conflicts with the Ninth Circuit's recent Watkins opinion, and the Eighth Circuit held that an analogous provision in the Federal Meat Inspection Act did not require a showing of materiality. *United States v. Jorgensen*, 144 F.3d 550 (8th Cir. 1998).

The materiality issue in this case is particularly important because of the broad regulatory sweep of the FD&C Act, and because of the government's theory of conviction in this case. The Indictment alleged an intent to obstruct FDA's regulatory scheme, but did not allege an intent to deprive FDA of money or property. Following the uniform pre-Neder authority from the circuit courts of appeal, the district court granted the government's request for an instruction that Defendants could be convicted if they intended to "defraud or mislead" the government, as opposed to defrauding consumers of their

products. Then the district court found a "fraud loss" at sentencing even in the absence of proof that consumers received ineffective drugs. See section V. below.

This dramatic extension of criminal liability under the FD&C Act is relatively new. Indeed, in a mid-'80s prosecution under the FD&C Act, the government conceded that it was being "innovative" in arguing that any conscious violations of 21 U.S.C. '331 constituted felonies because they would necessarily involve an intent to defraud the FDA. The Fifth Circuit at first expressed distaste for the government's theory:

> we observe that the theory would as a practical matter have the effect of rendering the "defraud and mislead" language of section 333(b) mere surplusage in the prosecution of any defendant charged with a conscious (and not publicly proclaimed) violation of section 331 – only inadvertent (or publicly announced) violations of section 331 would be misdemeanors, because all conscious (and not publicly confessed) violations would necessarily involve a deliberate evasion of established regulatory systems.

United States v. Haga, 821 F.2d 1036, 1044-45 & n.17 (5th Cir. 1987).

The absence of a specific federal statute dealing with steroids whose purchasers were not "defrauded" eventually led the Courts of Appeals, including the Fifth Circuit, to bless the theory of fraud on the FDA in prosecutions of steroids dealers. *United States v. Bradshaw*, 840 F.2d 871, 873-74 & n.4 (11th Cir. 1988); *United States v. Cambra*, 933 F.2d 752, 755 (9th Cir. 1991); *United States v. Mitcheltree*, 940 F.2d 1329 (10th Cir. 1991); *United States v. Arlen*, 947 F.2d 139, 142-43 (5th Cir. 1991).

This trend of criminalizing all knowing violations of FDA regulations, no matter how immaterial to consumers, not only violates Neder's reasoning, but also is a dangerous, and potentially limitless, expansion of the prosecution's discretion to expose selected pharmaceutical executives to felony sentences under the FD&C Act.

II. THERE IS A SIGNIFICANT SPLIT IN THE IRCUITS AS TO WHETHER CONGRESSONAL INTENT MAY OVERRIDE DRAFTING ERRORS IN THE PLAIN LANGUAGE OF CRIMINAL STATUTES.

As the Seventh Circuit's second opinion summarized:

> There was a gap between 1984 and 1990 where under the plain statutory language the failure to establish or maintain records under [21 U.S.C.] 355(k) was not subject to criminal penalties. This time gap is of import in this case; the defendants' conduct charged under [21 U.S.C.] 331(e) occurred in August of 1988, which raises the delicate question of whether their convictions for these violations may stand, given that the plain language of the statute did not penalize their conduct.

App. 6.

The Seventh Circuit's second opinion conceded that "[g]enerally, courts strictly construe criminal statutes against the government and in the defendant's favor," App. 6-7 (citations omitted), but also noted:

> Some courts have upheld the imposition of criminal penalties despite the presence of a typographical error in the statute. See *United States v. Lacher*, 134 U.S. 624, 625-32 (1890) . . .; *United States v. Graham*, 169 F.3d 787, 790-91 (3d Cir. 1999) . . .; *United States v. Warren*, 149 F.3d 825, 827-28 (8th Cir. 1998) . . .; *United States v. Rosetti Bros, Inc.* 671 F.2d 718, 720 (2d Cir. 1982) . . . ; *United States v. Scrimgeour*, 636 F.2d 1019, 1021-24 (5thCir. Unit B 1981) . . .; *United States v. Moore*, 198 U.S. App. D.C. 296, 613 F.2d 1029, 1039-45 (D.C. Cir. 1979)(same); *United States v. Babcock*, 174 U.S. App. D.C. 199, 530 F.2d 1051, 1053-54 (D.C. Cir. 1976) . . . .

App. 6-8 (case summaries and other citations omitted).

"However," the Seventh Circuit wrote, "some courts have held otherwise. See *United States v. Faygo Beverages, Inc.*, 733 F.2d 1168, 1170 (6th Cir. 1984) . . . ; *United States v. RSR Corp.*,

664 F.2d 1249, 1253-55 (Former 5th Cir. 1982) . . . ." App. 9 (case summaries omitted).

This question involves more than a split of authority on an issue that will continue to arise in different contexts in the future; it presents a fundamental question of democratic theory. We are a government of laws, not men. Requiring Congress to specify criminal conduct is more than a question of notice to criminal defendants; it is a restraint on the power of the prosecution to create crimes through interpretations of legislative intent.

III. THE SEVENTH CIRCUIT'S REJECTION OF AN EX POST FACTO CHALLENGE TO A GUIDELINES CROSS-REFERENCE ADOPTED AFTER DEFENDNTS' CONDUCT CONFLICTED WITH UNIFORM PRECEDENT FROM OTHER CIRCUITS.

At sentencing, Defendants contended that the district court should apply U.S.S.G. 2N2.1, "Violations of Statutes and Regulations Dealing With Any . . . Drug." 2N2.1 carries an offense level of six, which reflects the pre-guideline sentencing experience with violations of the FD&C Act, when defendants in cases like this one, with no demonstrated harm to consumers, routinely received probationary sentences. Application Note 1 to 2N2.1 provides, "[t]his guideline assumes a regulatory offense that involved knowing or reckless conduct."

All of the substantive counts of conviction occurred prior to November 1, 1989. The district court found that the government had not proved by a preponderance of the evidence that Defendants' criminal conduct continued after November 1, 1991. Tr. 6/16/00 at 82. Yet the Seventh Circuit upheld the district court's decision to apply U.S.S.G. 2F1.1, relying on the cross reference in 2N2.1(b)("If the offense involved fraud, apply section 2F1.1 (Fraud and Deceit)"), and rejecting Defendants' ex post facto argument that the Sentencing Commission had not adopted that cross reference

until November 1, 1992, after the crimes of conviction occurred. The Seventh Circuit held that "judges must apply the Guidelines in force when a defendant is sentenced." App. 11.

The panel's rejection of Defendants' ex post facto argument by holding that "judges must apply the Guidelines in force when a defendant is sentenced" conflicts with relevant precedent of this Court and the uniform precedent of the circuit courts of appeal on an important federal question. *Weaver v. Graham*, 450 U.S. 24 (1981); *United States v. Harotunian*, 920 F.2d 1040, 1041-42 (1st Cir. 1990); *United States v. Fitzgerald*, 232 F.3d 315, 318-19 (2d Cir. 2000) (per curiam); *United States v. Kopp*, 951 F.2d 521, 526 (3d Cir. 1991); *United States v. Neilssen*, 136 F.3d 965, 969 (4th Cir. 1998); *United States v.Fox*, 248 F.3d 394, 410 (5th Cir. 2001); *United States v. Cseplo*, 42 F.3d 360, 362 (6th Cir. 1994); *United States v. Behler*, 14 F.3d 1264, 1271 (8th Cir. 1994); *United States v. Steffan*, 251 F.3d 1273, 1277 (9th Cir. 2001); *United States v. Easterling*, 157 F.3d 1220, 1225 (10th Cir. 1998); *United States v. Bailey*, 123 F.3d 1381, 1403 (11th Cir.1997); *United States v. Clark*, 303 U.S. App. D.C. 435, 8 F.3d 839, 844 (D.C. Cir. 1993); see also U.S.S.G. §§ 1B1.11(b) (2001) ("If the court determines that use of the Guidelines Manual in effect on the date that the defendant is sentenced would violate the ex post facto clause of the United States Constitution, the court shall use the Guidelines Manual in effect on the date that the offense of conviction was committed.").

IV. THERE IS A SPLIT IN THE CIRCUITS AS TO WHETHER UNREBUTTED DEFENSE EXPERT TESTIMONY DENYING AN ELEMENT OF THE OFFENSE RENDERS THE GOVERNMENT'S EVIDENCE INSUFFICIENT AS A MATTER OF LAW.

Defense expert John R. Robyt, a Professor of Biochemistry for 31 years, testified that the leaks in the 55-gallon drums did

not present any danger to the Lactulose. He explained that Lactulose would not support the growth of microorganisms and would not absorb organic volatiles. Tr. 4256-62, 4287-90. The government did not rebut Robyt's testimony; its two CGMP "experts" knew nothing about Lactulose's chemical properties. Tr. 630-31, 708, 724, 3373-79, 3316-18.

The Seventh Circuit's affirmance without addressing Dr. Robyt's testimony split with precedent from other circuits finding that unrebutted defense expert testimony denying an element of the offense rendered the government's evidence insufficient as a matter of law. *United States v. Parks*, 460 F.2d 736 (5th Cir. 1972) (government psychiatric expert insufficient to rebut defense experts where government's expert did not have necessary facts as background for opinion); *United States v. Bass*, 490 F.2d 846 (5th Cir. 1974)(unrebutted defense expert testimony of insanity rendered government's evidence insufficient); *United States v. Rutgard*, 116 F.3d 1270, 1283 (9th Cir. 1974)(two expert ophthalmologists disagreed about whether cataract surgery should have been performed; "no reasonable juror could conclude beyond a reasonable doubt that Rutgard knew the surgery on Socorro Manzo's left eye was medically unnecessary; the evidence is insufficient to establish fraud.")

V. THE SEVENTH CIRCUIT'S HOLDING THAT VIOLATIONS OF A REGULATORY SCHEME, NOT "THE MEDICAL [IN]EFFECTIVENESS OF THE DRUG," IS SUFFICIENT TO PROVE A "FRAUD LOSS" UNDER U.S.S.G. 2F1.1 CONFLICTS WITH DECISIONS FROM OTHER CIRCUITS.

At sentencing, Defendants contended that there was no "fraud loss" under U.S.S.G. 2F1.1, because the government had not proved that consumers received ineffective drugs. However, the district court held that the gross sales figures for the lots of conviction constituted a fraud loss. The Seventh Circuit upheld the district court's finding of fraud loss, disagreeing with the Fourth Circuit's holding in *United States v. Chatterji*, 46 F.3d 1336 (4th Cir. 1995), and declining to apply *United States v. Maurello*, 76 F.3d 1304 (3d Cir. 1996) by analogy. The panel wrote: "[t]he medical effectiveness of the drug or its dangerousness after adulteration ought not to be the core of the inquiry; . . . there was indeed loss to consumers because consumers bought drugs under the false belief that they were in full compliance with the law." App. 14.

The Seventh Circuit's opinion that violations of a regulatory scheme cause a fraud loss to consumers, even when the district court found that the government had not proved that consumers received ineffective or unsafe drugs, conflicts with approaches of other circuit courts of appeals in determining fraud loss under 2F1.1. *United States v. Maurello*, 76 F.3d 1304, 1312 (3d Cir. 1996)("[t]o the extent that the unauthorized services provided by defendant [an unlicensed attorney] have not harmed their recipients, but to the contrary have benefited them, we conclude that defendant's base offense level should not be enhanced."); *United States v. Chatterji*, 46 F.3d 1336 (4th Cir. 1995)(violations of regulatory scheme that do not affect safety or efficacy of drugs do not result in fraud loss), and *United States v. Marcus*, 82 F.3d 606 (4th Cir. 1996)(violations of regulatory scheme that would affect bioavailability of drugs did cause fraud loss); *United States v.*

Haas,171 F.3d 259, 269-70 (5th Cir. 1999) ("there would be no economic harm done to the customers if they consumed the drugs in ignorance of the lack of FDA approval and those drugs performed just as well as FDA-approved drugs," but holding that defendant's gain, in the form of net profits, could be used to enhance sentence even in the absence of loss); *United States v. Barnes*, 125 F.3d 1287 (9th Cir. 1997) (district court erred in using total amount of billings attributable to person impersonating a doctor when, absent his salary, there was no monetary loss to clinic, donors or customers; must give credit for amount of satisfactory services); *United States v. Haddock*, 12 F.3d 950, 960-61 (10th Cir.1993) ("If gain to the defendant does not correspond to any actual, intended, or probable loss, the defendant's gain is not a reasonable estimate of loss."); *United States v. Prigmore*, 1996 U.S.Dist. Lexis 11695 (D.Mass. 1996)(no loss enhancement under 2F1.1 where unapproved heart catheters did not work any worse than approved catheters).

In a context where the government denies that materiality is an element of violations of the FD&C Act, adoption of the Seventh Circuit's rationale subjects pharmaceutical companies and executives to enormous loss enhancements and lengthy prison terms even for regulatory violations that do not result in any harm or actual losses to consumers.

VI. THE GOVERNMENT HAS SUCCESSFULLY MISLED THE SEVENTH CIRCUIT TWICE

After remand, Defendants filed a renewed motion for a new trial, contending that if the jury had heard the government's admissions during appeal that the Lactulose was medically effective and stable, the outcome of the trial would have been different. While agreeing that the government had changed its position on appeal, the district court denied the motion, believing that the Seventh Circuit's prior decision precluded it from reaching the merits. App. 18-19.

Defendants argued that a decline in pH did not correlate to any significant drop in medical effectiveness or potency. The government argued that a decline in pH, even within the approved pH specifications, showed "degradation" and loss of medical effectiveness. The Brady material in FDA's files proved there was no correlation between a decline in pH and the potency of Lactulose. There is not room in this petition to list the dozens of occasions when the government linked a decline in pH to a decline in potency, and argued or suggested that the Lactulose was unstable and "degraded" and "expired" before the addition of sodium hydroxide. Here are a few salient examples:

Count Three of the Indictment alleged that lot 52-230 was adulterated on August 12, 1998 (the date of the alleged addition of sodium hydroxide) in three separate ways, including that "(1) this drug product consisted in part of a decomposed substance, namely decomposed lactulose raw material."

Government counsel told the jury during closing argument that "Lactulose is an unstable sugar." Tr. 5612 (emphasis added). The government submitted a jury instruction alleging that "Lactulose lot 52-230-P was adulterated in that this drug product consisted in part of a decomposed substance, namely decomposed Lactulose raw material. If you unanimously find this to be the case, you should find this lot of Lactulose adulterated." (Emphasis added). The district court read that instruction to the jury. Tr. 5840.

The government agreed to a modified version of Alra Requested Instruction No. 4, which provided:

> "Decomposed" means more than that the Lactulose active ingredient had begun to degrade. . . The government must prove beyond a reasonable doubt that at or about the time alleged in the particular count the Lactulose active ingredient had decomposed so that it no longer met applicable testing

> specifications in order for you to find that the Lactulose lots. . .were "decomposed."

(Emphasis added). The district court read that instruction to the jury. Tr. 5842. In other words, the government asked the jury to convict on its allegation that the Lactulose was medically ineffective before the addition of sodium hydroxide.

The government called Dr. John Senior, a gastroenterologist, to testify about the effect of "degraded" Lactulose. As the district court stated at a post-trial hearing on September 11, 1996:

> [o]ne of the most impressive witnesses at the trial, if not the most impressive witness, was the Government's expert, Dr. Senior. At page 27 of the transcript of his testimony, he is asked, I believe, by [Government counsel]: "Question: if Lactulose is degraded into monosaccharide components, would it work to treat portal systemic encephalopathy? Answer: No, it won't work if it is degraded or split because the split products of Lactulose are fructose and galactoses which are easily absorbed sugars. They are gone. They never get to the colon." And he goes on . . . to talk about how, if the Lactulose is degraded, it won't be medically effective. Then he is asked at line 17 of page 28: "Question: And would a physician be able to ascertain what was wrong if Lactulose had broken down into disaccharide forms?" Now, there would be absolutely no purpose in asking that question, it seems to me, unless the Government was contending that the question was relevant to the fact situation before the jury. And Dr. Senior, in what was, in my distinct recollection, an absolutely devastating answer said the following: "That makes it very hard on the physician because a lot is going on in these sick patients. They have got a lot of problems, and the last thing a physician is going to think of when he prescribes a drug is that it isn't what it is supposed to be." . . .

Motions hearing, 9/11/96 at 10-11 (emphasis added).

The Bhutanis testified that they would have had no reason to adjust the pH of the Lactulose Syrup. Tr. 5003, 5250-54. At trial, the government attacked Mrs. Bhutani's credibility, suggesting in repeated questioning that she knew, or should have known, that the product was not stable when it was released. Tr. 5075-84. Government counsel began his cross-examination of Dr. Bhutani by challenging Dr. Bhutani's assertion that the Lactulose was stable even though it was several years old. Tr. 5387-94.

The same three judges who adopted the government's mischaracterization of the trial on the first appeal did not address any specifics from the record. Instead, they wrote conclusory language that "[the government's] focus at trial was not that the Lactulose was outside of the acceptable pH range or medically ineffective, but rather the fact that the defendants added sodium hydroxide to the Lactulose lots because they wanted the 1986 lots to have a pH similar to the 1988 lots so that they could bear the same expiration date and be sold." App. 2.

This erroneous conclusion relied upon speculation by government counsel during rebuttal closing argument that Defendants raised the pH so that if wholesale customers later "checked the pH, it would appear that this stuff was new." Tr. 5804-05. In briefing, Defendants have repeatedly pointed out that this last-minute argument had no factual basis, because the name brand manufacturer of Lactulose, which had previously monopolized the U.S. market, released its product with a pH in the range of 4.0-5.0, well below the pH of Alra's two Lactulose lots. There was no evidence that wholesalers would have rejected the two lots because of minor variations in pH well within FDA-approved specifications.

The government has repeatedly claimed that this speculative afterthought was its sole theory of motive, saying that when government counsel used the words "decomposed," "degraded," and "expired," they really meant "aged, but still stable and medically effective." That claim is desperate and

linguistically absurd. The district court's quotations of the government's arguments demonstrate that substituting the phrase "aged, but still stable and medically effective" every time government counsel used the words "decomposed," "degraded," and "expired" changes the tone and meaning of the government's arguments beyond recognition. App. 39-48.

Indeed, during Rule 29 argument, asked whether the decomposition happened after the alleged addition of sodium hydroxide, government counsel responded, "No, your Honor. . . . Lactulose by 18 months after its manufacture would be decomposed to the degree that it could no longer be used as medicine." Tr. 4232-3.

The government's last-minute, speculative argument about wholesale customers comparing pH values did not erase all the government's efforts to prove that a decline in pH was evidence of a decline in medical effectiveness, nor erase all the government's inflammatory arguments that Defendants sold "decomposed," "degraded," and "expired" Lactulose without regard for patients' health. The district judge who presided over the ten-week trial did not "misunderstand" or "fail to remember" the government's trial theory. The government's egregious mischaracterization of the record warrants exercise of this Court's supervisory authority.

CONCLUSION

The petition for a writ of certiorari should be granted.

Mark London
(Counsel of Record)
Christopher B. Mead
London & Mead
1225 19th Street, N.W., Suite 320
Washington, D.C. 20036
(202) 331-3334

Mark L. Shaw
33 North County Street
Suite 302
Waukegan, Illinois 60085
(847) 244-4696

Counsel for Petitioners
Baldev Rag Bhutani and
Alra Laboratories, Inc.

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IN THE
UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

Nos. 00-1523, 00-2679

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

BALDEV RAJ BHUTANI
and ALRA LABORATORIES, INC.,

Defendants-Appellants.

Appeals from the United States District Court
for the Northern District of Illinois, Eastern Division.
No. 93 CR 585 - **John F. Grady, *Judge.***

ARGUED APRIL 5, 2001
ENTERED SEPTEMBER 12, 2001

Before BAUER, RIPPLE, and EVANS, *Circuit Judges.*

Bauer, *Circuit Judge.* A jury found defendants Baldev Raj Bhutani, Neelam Bhutani, and ALRA Laboratories, Inc. guilty of various violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* The defendants moved for a new trial, which the district court granted, finding that the government violated *Brady v. Maryland,* 373 U.S. 83, 10 L. Ed. 2d 215, 83 S. Ct. 1194 (1963). The government appealed, and in *United States v. Bhutai,* 175 F.3d 572 (7th Cir. 1999) we reversed and remanded the case for sentencing. On remand, the defendants again moved for a new trial, which the district

court denied. Assuming familiarity with our first opinion, we consider the appeal by the defendants (Neelam does not appeal) from that denial. For the following reasons, we affirm.

A.

The defendants believe that the government's position in the first appeal contradicted its trial theory and that the government's [**2] appellate position is newly discovered evidence, and that if the jury had heard the government's appellate theory it would have decided the case differently. Specifically, they contend that at trial the government said that the defendants had added sodium hydroxide to decomposed Lactulose in hopes of concealing its medical ineffectiveness, but on appeal admitted that the Lactulose was medically effective by iterating that it was within the accepted pH range before the addition of sodium hydroxide. On remand, the district court agreed with the defendants that the government had changed its theory, but the district court refused to entertain the argument, believing that it was foreclosed from doing so since we had held otherwise in our first opinion in this case.

The government counters that its focus at trial was not that the Lactulose was outside of the acceptable pH range or medically ineffective, but rather the fact that the defendants added sodium hydroxide to the Lactulose lots because they wanted the 1986 lots to have a pH similar [*664] to the 1988 lots so that they could bear the same expiration date and be sold. The government's position was that the defendants masked the fact that [**3] the Lactulose was degrading and past its expiration date in order to make money.

We agree with the government. A second read of the trial transcript reveals that the government's position at trial and on appeal has been consistent. The government did not show at trial that the Lactulose was outside the accepted pH range or medically ineffective; rather it admitted that the pH was at all

times within range, but that it was dropping, which signaled degradation, and in order to mask any degradation the defendants raised the pH by adding sodium hydroxide so that the fact that it was being sold past its expiration date could not be detected. The medical efficacy of the Lactulose was only mentioned by the government to explain the significance of expiration dating to the jury. The government wanted to explain why expiration dates are imposed in order to counter the defense theory that the defendants did not intend to put an adulterated product on the market because Lactulose could be stable and medically effective beyond the artificially imposed expiration date assigned by the "paperwork bureaucracy" known as the FDA. The defense again mischaracterizes the thrust of the government's case [**4] and regurgitates its argument from the last appeal, the only difference being that in the first appeal they argued that the newly discovered evidence was the U.S.P. recommendation, see 175 F.3d at 578-79, and here they point to the government's switch in theories. This supposed difference does not affect our decision. There is no new evidence that would have altered the outcome of this case.

B.

The defendants submit that reversal is justified because the district court abused its discretion, *see United States v. Butler*, 71 F.3d 243, 250 (7th Cir. 1995), by permitting the government to elicit impermissibly prejudicial testimony from Dr. John Senior, offered as an expert in gastroenterology and liver disease, see Trial Tr. at 1691 (December 28, 1995), about the medical consequences of taking ineffective Lactulose. The defendants claim that Dr. Senior testified that patients could die from ingesting ineffective Lactulose. Before Dr. Senior testified, the district court had admonished the government to avoid introducing this sort of testimony. The defendants believe that the government violated this admonition.

Contrary to the defendants' characterization [**5] of Dr. Senior's testimony, the transcript reveals that he did not testify in an impermissibly prejudicial manner. Dr. Senior explained that Lactulose works as a substitute liver for patients with liver disease, and that Lactulose would be ineffective if it had degraded into its component parts because the separate sugars would be absorbed into the small intestine before reaching the colon. He also testified that it would be impossible for a physician to know that Lactulose had degraded to the point of ineffectiveness, and therefore a physician might erroneously determine that the Lactulose was ineffective for a patient for some other reason.

The sole mention of the possibility of death from ingesting ineffective Lactulose was not presented by the government, but was elicited on cross-examination by the defense:

Q. [Mr. Branding, Attorney for ALRA] And [Lactulose] doesn't cure the underlying liver disease, does it?

A. Of course not.

Q. It's only -

[*665] A. It's only a compensation for a failed organ.

Q. It's used to treat the symptoms?

A. It's used to treat--it's not just symptoms. It's a whole syndrome that may kill. It's not just symptoms.

Encephalopathy [**6] due to liver failure may be fatal. It's not just symptoms.

Trial Tr. at 1710-11 (December 28, 1995). The testimony defendants complain about was never offered, and thus there was no abuse of discretion by the district court.

C.

The defendants argue that Count Four, which charged that the defendants "on or about August 12, 1988 ... with intent to defraud and mislead, failed to establish and maintain accurate drug manufacturing batch production records for the generic drug product, Lactulose Syrup USP" in violation of 21 U.S.C. § 331(e), along with the correlating conspiracy charge in Count One, failed to state a crime for which they could be convicted.

In 1938, Congress enacted the FDCA pursuant to its authority to regulate interstate commerce in order to protect the public from dangerous food and drug products. In 1962, Congress amended the FDCA, adding § 355(j) to require drug manufacturers to establish or maintain records about the manufacture and testing of drugs. *See* The Drug Amendments of 1962, Pub. L. No. 87-781, § 103(a), 76 Stat. 780. Thereafter, the failure to establish or maintain records under § 331(j) was a prohibited act under [**7] § 331(e) and subject to the imposition of criminal penalties under § 333, such as imprisonment, fine, or both.

In 1984, Congress amended the FDCA and the federal patent laws to help make available more low cost drugs by creating an abbreviated procedure for FDA approval of generic drug applications. *See* Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585; *see also National Ass'n of Pharm. Mfrs., Inc. v. Ayerst Labs.*, 850 F.2d 904, 907 (2d Cir. 1988). Congress enacted this new abbreviated drug approval process under § 355(j) and redesignated the old § 355(j) concerning recordkeeping as § 355(k). However, Congress did *not* alter § 331(e). Thus, § 331(e) still instructed that the failure to establish or maintain records under § 355(j) was subject to criminal penalties, even

though the new § 355(j) did not require recordkeeping. Whether intentional or not, the penalties for failing to establish or maintain records had been in effect eliminated.

In 1990, Congress passed a short, technical amendment, which stated: "Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 331(e)) [**8] is amended by striking out 'or (j)' and inserting in lieu thereof 'or (k).'" Vaccine & Immunization Amendments of 1990, Pub. L. No. 101-502, 104 Stat. 1285. Thus, by simply replacing "(j)" with "(k)," § 331(e) again clearly subjected violators to the same criminal penalties as they had been for more than two decades prior to 1984 for failing to establish or maintain records.

However, there was a gap between 1984 and 1990 where under the plain statutory language the failure to establish or maintain records under § 355(k) was not subject to criminal penalties. This time gap is of import to this case; the defendants' conduct charged under § 331(e) occurred in August of 1988, which raises the delicate question of whether their convictions for these violations may stand, given that the plain language of the statute did not penalize their conduct. As noted, the defendants argue that under the plain language [*666] of the statute they cannot be penalized for failing to establish and maintain records. The government argues that the elimination of the penalty was a scrivener's snafu, and criticizes the defendants' hyper-technical and illogical reading of the statute. This question has all of the [**9] trappings of a law school hypothetical, but with real-world consequences, so although the defendants' brief fails to support this argument with case law discussion or even citation, we nonetheless address this important issue of criminal law and statutory construction.

Generally, courts strictly construe criminal statutes against the government and in the defendant's favor. *See Barrett v. United States,* 423 U.S. 212, 218, 46 L. Ed. 2d 450, 96 S. Ct. 498 (1976); 3 Norman J. Singer, Sutherland Statutory Construction

§ 59.03 (5th ed. 1992). This is so to ensure that people are fairly warned about what sort of conduct may expose them to criminal penalties and what sort of penalty may be imposed. *See United States v. Bass*, 404 U.S. 336, 348, 30 L. Ed. 2d 488, 92 S. Ct. 515 (1971); 3 Sutherland Statutory Construction § 59.03. But, in strictly construing a statute, courts ought not deprive it of the obvious meaning intended by Congress, nor abandon common sense. *See United States v. Moore*, 423 U.S. 122, 145, 46 L. Ed. 2d 333, 96 S. Ct. 335 (1975); 3 Sutherland Statutory Construction § 59.06.

Some courts have upheld the imposition of criminal penalties [**10] despite the presence of a typographical error in the statute. *See United States v. Lacher*, 134 U.S. 624, 625-32, 33 L. Ed. 1080, 10 S. Ct. 625 (1890) (upholding conviction for embezzling a letter containing an article of value under 18 U.S.C. § 318 even though after revision of the statute the wording was altered because "the intention to impose a penalty on [the] commission [of the offense] cannot reasonably be denied; and, although the apparent grammatical construction might be otherwise, the true meaning, if clearly ascertained, ought to prevail"); *United States v. Graham*, 169 F.3d 787, 790-91 (3d Cir. 1999) (upholding a defendant's sentence for illegally reentering the United States after finding that Congress intended that the actual term of imprisonment imposed determines whether a defendant is classified as an "aggravated felon" under 8 U.S.C. § 1101(a)(43) despite the fact that the statutory section was "obviously missing a crucial verb"); *United States v. Warren*, 149 F.3d 825, 827-28 (8th Cir. 1998) (affirming the defendant's sentence of 151 months for manufacturing 32,000 grams of methamphetamine [**11] under 21 U.S.C. § 841(b)(1) even though "at the time of [the] offense, because of a typographical error, the same amount of a quantity of a mixture -- 100 grams -- was listed as triggering both the five-year and the ten-year mandatory minimum sentences," because Congress intended drug trafficking penalties to be graduated according to drug quantity); *United*

States v. Rossetti Bros, Inc., 671 F.2d 718, 720 (2d Cir. 1982) ("Plainly, Congress did not intend its recodification [of the Interstate Commerce Act] to reduce the reach of [its] penalty, but intended merely to transplant that section, renumbered, into the recodified portion .... Congressional drafters unfortunately overlooked [this], but, when construed in light of the intent of Congress and in light of common sense, that section clearly applies to the regulations here in question."); *United States v. Scrimgeour*, 636 F.2d 1019, 1021-24 (5th Cir. Unit B 1981) (reversing dismissal of indictment under 18 U.S.C. § 1623(d) for making false declarations before a grand jury because in finding Congress' intention in enacting the statute, the court believed [**12] Congress inadvertently used an "or" in the statute but meant to use "and"); *United* [*667] *States v. Moore*, 198 U.S. App. D.C. 296, 613 F.2d 1029, 1039-45 (D.C. Cir. 1979) (same); *United States v. Babcock*, 174 U.S. App. D.C. 199, 530 F.2d 1051, 1053-54 (D.C. Cir. 1976) (holding that, in light of "an inadvertent change" by Congress when reorganizing and renumbering the statute, 2 U.S.C. § 441(b) was not to be interpreted to mean that a misdemeanor violation under § 440 precluded being sentenced to imprisonment); *cf. Whitfield v. Scully*, 241 F.3d 264, 272 (2d Cir. 2001) ("Although the statute refers to [28 U.S.C.] § 1915(a)(2) for the manner of payment, we have recognized that this reference is a typographical error (as it makes the statute unintelligible) and that the actual process for payment of costs is instead described in § 1915(b)(2)."); *Estate of Kunze v. C.I.R.*, 233 F.3d 948, 953 (7th Cir. 2000) ("The erroneous cross-reference in [26 U.S.C. § 7430(c)(4)(D)] to a misnumbered subparagraph in (4)(A) can hardly be construed to have changed the legislative intent ... or to have affected [**13] the substantive rights of the parties. The import of the subsection remains clear, in spite of the typo."); *In re Chateaugay Corp.*, 89 F.3d 942, 952 (2d Cir. 1996) (agreeing with other courts that the improperly renumbered subsections in 11 U.S.C. § 507 were the result of typographical errors by Congress rather than substantive changes in the law).

However, some courts have held otherwise. *See United States v. Faygo Beverages, Inc.*, 733 F.2d 1168, 1170 (6th Cir. 1984) (recognizing that Congress unintentionally eliminated a penalty section in recodifying the Interstate Commerce Act, but holding that the defendant was not subject to criminal penalty for his conduct because "it would be unreasonable to require persons confronted with the plain language of a criminal statute to go beyond that statute in order to determine whether Congress really meant what it clearly said"); *United States v. RSR Corp.*, 664 F.2d 1249, 1253-55 (Former 5th Cir. 1982) (noting that Congress inadvertently changed a penalty section in recodifying the Interstate Commerce Act, but holding that the defendant was not subject to criminal penalty for his [**14] conduct, stating "although this is what Congress clearly meant to say, intended to say, and wanted to say, still Congress did not say it").

While the plain language of the FDCA clearly prohibited the failure to establish or maintain records, criminal penalties were not clearly imposed. Nevertheless, we agree with the reasoning found in the former set of cases rather than the latter because strictly reading and applying the FDCA as it was at the time of the offense in question would put the plain language at odds with the statute's purpose and intent. There is no indication in the legislative history that in amending the FDCA Congress intended to eliminate the penalties. The Law Revision Counsel of the House of Representatives, who prepares and publishes the U.S. Code, even placed a footnote in the 1988 edition of the U.S. Code in § 331(e) after the proscription on failing to keep records under § 355(k), and noted that § 335(j) had been redesignated as § 355(k). Thus, it seems that the failure to cross-reference the sections was interpreted as a mere typo by the Law Revision Counsel. Also, we agree with the government that Congress would not have eliminated the penalties for failing [**15] to establish or maintain records in this part of the statute while retaining the penalties for failing to do so under other sections.

Furthermore, the government points out that the 1984 amendments broadened the recordkeeping requirements in the redesignated § 355(k), and that Congress would not have intentionally broadened the requirements and at the same time have eliminated the penalties for not complying with the requirements.

[*668] Finally, the defendants do not argue that because of the typographical error they lacked notice; nor could they since they maintained records believing that they were required to (although they did so inadequately, as this case reveals) under the FDCA. Therefore, we hold that the failure to establish or maintain records under § 355(k) was subject to criminal penalties despite the typographical error in § 331(e) between 1984 and 1990.

D.

Baldev Bhutani also raises several challenges to his sentence imposed under U.S.S.G. § 2F1.1 (2000). "The district court's choice of which guideline to apply is a question of law, and we review this choice *de novo*," *United States v. Andersen*, 45 F.3d 217, 219 (7th Cir. 1995); we review factual determinations [**16] for clear error, *see United States v. Vitek Supply Corp.*, 144 F.3d 476, 490 (7th Cir. 1998).

First, the defendant finds error in the district court's choice of guideline to apply, claiming that he ought to have been sentenced under § 2N2.1(a) rather than § 2F1.1. Section 2N2.1(a) covers violations of statutes and regulations dealing with, among other things, drug products, and assigns a base offense level of six to such violations; however, subsection (b)(1) instructs: "if the offense involved fraud, apply § 2F1.1 (Fraud and Deceit)." Section 2F1.1 "also has a base offense level of six, but provides for substantial increases in offense level based on the amount of loss." *Andersen*, 45 F.3d at 219. Bhutani's argument turns on the notion that § 2N2.1(a) applies because his wrongs were "knowing, technical" violations of the

FDCA, and not as serious as those of other companies that have been prosecuted. This argument is without merit as there is substantial evidence of fraud in this case. *See, e.g., id.* at 219-20.

Second, he submits that § 2N2.1(b)(1) does not apply to his case since it was made effective on November 1, 1992, but "the offenses [**17] of conviction all occurred prior to November 1, 1992." This is of no matter since "judges must apply the Guidelines in force when a defendant is sentenced." *United States v. Perez*, 249 F.3d 583, 584 (7th Cir. 2001) (per curiam). Bhutani was sentenced on February 15, 2000, and subsection (b)(1) was then in effect, thus it is applicable.

Third, the defendant disputes how the district court measured loss. As noted, § 2F1.1 assigns a base offense level of six, which is increased based on the amount of loss attributed to the fraud. In calculating the loss, the district court is not required under the Sentencing Guidelines to "compute the loss with precision; the court need only make a reasonable estimate of the loss based on the information available." *United States v. Duncan*, 230 F.3d 980, 985 (7th Cir. 2000); *see* U.S.S.G. § 2F1.1, cmt. 9. If it has been shown that the victims of the fraud suffered a loss and a more precise way of measuring the loss is unavailable, the amount of the defendant's gain may provide a reasonable estimate of the loss. *See Andersen*, 45 F.3d at 221.

Directing us to *United States v. Chatterji*, 46 F.3d 1336 (4th Cir. 1995), [**18] the defendant maintains that his gain was not the appropriate measure because there was no actual loss to consumers as none of the drugs were shown to be medically ineffective and there was no evidence that anyone fell ill or died. He argues that the calculation should not be based on whether the consumers got what they bargained for, but rather ought to be based on whether the consumers got medically effective drugs.

[*669] In *Chatterji*, the defendant, sentenced under U.S.S.G. § 2F1.1, submitted two abbreviated new drug

applications to the FDA, which were approved. *See id.* at 1338-40. The defendant had submitted false batch records in its application for one of the drugs, and for the other had changed the formula by adding more of an inactive ingredient after its application had been approved without seeking further FDA approval. The district court held that loss should be measured by the defendant's gain from the sale of the drugs because the defendant's fraud voided the FDA approval, thereby stripping the drugs of market value. *See id.* at 1340. The Fourth Circuit, over dissent, reversed, finding that the defendant's gain was not the appropriate measure of loss [**19] because consumers got medically effective drugs that were exactly what they purported to be. *See id.* at 1340-43.

Relying on *United States v. Marcus*, 82 F.3d 606 (4th Cir. 1996), the government in our case argues that there was loss to consumers because consumers paid for-FDA-approved drugs, but received drugs that were not manufactured according to the FDCA and FDA regulations; therefore, the government argues that the amount of the defendant's gain is an appropriate measure of loss.

In *Marcus*, the defendant, sentenced under § 2F1.1, had obtained FDA approval to manufacture a drug, but changed the formula by adding two additional inactive ingredients without obtaining additional FDA approval. *See id.* at 607-08. The district court found that the defendant's gain was the appropriate measure of loss because the drug did not meet FDA specifications, and therefore, had no value. *See id.* at 608. The court distinguished *Chatterji*, which the Fourth Circuit affirmed, reasoning that the formula modification in *Chatterji* "was merely an insignificant change that implicated only the shelf life of the drug," and not the safety or medical efficacy; [**20] however, the formula modification here had a bearing on the medical effectiveness, which would require additional testing to determine whether the drug was still safe and effective. *Id.* at 610.

In this case, the district court agreed with the government's position and reasoned:

I find the analysis in the *Marcus* case from the Fourth Circuit to be persuasive. I understand that the defendants believe *Marcus* is distinguishable on the basis that the defendant there agreed that there was an issue as to whether the drug involved there was the bioequivalent of the patented drug.

I don't regard that as a distinguishing feature of the case, because whether the defendants stipulate to it or not, and certainly they do not in this case, I find that there was an issue as to whether these drugs had been properly manufactured.

I'm not saying that there was an issue as to whether they would be injurious to health or necessarily even an issue as to whether they would be effective for their pharmaceutical purpose. What I find, rather, is that there was an issue as to whether they had been manufactured in such a way that the consumers of those drugs were being sold something other [**21] than what they thought they were buying.

I don't think that any consumer of any of those drugs would have bought those drugs had the consumer known what had happened to them.

***

And I think the essence of the loss here to the consumers was the same thing fact [sic] that the *Marcus* case was [*670] talking about, namely, the fact that they didn't get the FDA-approved manufactured drugs that they thought they were getting.

And I emphasize that I don't think *Marcus* applies only in the situation where the drugs could be dangerous. ...

Sentencing Hr'g Tr. at 23-24 (February 15, 2000). The district court based the amount of loss on the defendant's gain,

which it estimated at over $ 200,000, thereby assigning Bhutani a base offense level of fourteen. *See* U.S.S.G. § 2F1.1(b)(1)(I).

While we do not agree with the district court's reading of *Marcus* or his reliance on it, we wholly adopt the core of its rationale. Indeed, we find the district court's reasoning to be more sound than that in *Chatterji* and *Marcus*. n1 The medical effectiveness of the drug or its dangerousness after adulteration ought not be the core of the inquiry; rather, the district court was justified in determining [**22] that there was a loss because consumers did not get what they bargained for. We agree with the district court's decision that there was indeed loss to consumers because consumers bought drugs under the false belief that they were in full compliance with the law.

n1 We decline the defendant's invitation to apply *United States v. Maurello*, 76 F.3d 1304 (3d Cir. 1996) by analogy to this case. We also find our decision in Vitek Supply inapplicable because it dealt with whether loss to competitors and down-stream consumers was to be included in the loss calculation. *See* 144 F.3d at 490-92.

However, the defendant points out that in *Andersen* we held that the defendant's gain was not the appropriate measure of loss when there was "no clear evidence that customers or consumers suffered any loss." 45 F.3d at 221. We so held, in part, because the drugs in that case were sold in hand-labeled containers and the customers were aware that the drugs were not FDA approved. *See* 45 F.3d at 221. [**23] That is not so here; here consumers bargained for FDA-approved drugs that were in compliance with the law. This they did not get. We agree with the district court's determination of what constitutes loss in this sort of case, and that the defendant's gain is the appropriate measure of that loss.

E.

The bulk of the defendants' brief is tinged with hyberbole, lamenting that they ought not to have been prosecuted because what they may have done was not so bad compared to what others have done and that their industry is overregulated by the FDA. The judiciary is not the branch to hear these beefs; rather, they ought to be raised with Congress, who makes the law, and prosecutors, who have broad discretion in instituting criminal proceedings. Furthermore, many of the disputes are no more than an invitation to reweigh the evidence based on the defendants' attempt to retry this case on appeal. We are at ease with the jury's work in weighing evidence and assessing credibility and will not engage in second-guessing. The other arguments of the defendants are equally without merit and we shall not address them further.

AFFIRMED.

IN THE
UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

Nos. 00-1523, 00-2679

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

BALDEV RAJ BHUTANI and
ALRA LABORATORIES, INC.,

Defendants-Appellants.

Appeal from the United States District Court
for the Northern District of Illinois, Eastern Division.
No. 93 CR 585-**John F. Grady**, ***Judge.***

ENTERED NOVEMBER 28, 2001

Before BAUER, RIPPLE, and EVANS, *Circuit Judges.*

ORDER

Upon consideration of the defendants' motion to stay issuance of mandate pending disposition of petition for writ of certiorari, filed November 21, 2001, by counsel, it is ordered that the motion is granted. The mandate in these appeals is stayed pending the filing of a petition for writ of certiorari.

IN THE
UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

Nos. 00-1523, 00-2679

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

BALDEV RAJ BHUTANI and
ALRA LABORATORIES, INC.,

Defendants-Appellants.

Appeal from the United States District Court
for the Northern District of Illinois, Eastern Division.
No. 93 CR 585-**John F. Grady, *Judge.***

ENTERED NOVEMBER 14, 2001

Before BAUER, RIPPLE, and EVANS, *Circuit Judges.*

ORDER

On consideration of the petition for [*2] rehearing and petition for rehearing *en banc* filed in the above-captioned case by defendants-appellants, no judge in active service has requested a vote thereon and all of the judges on the original panel have voted to deny. Therefore, the petition for rehearing is hereby DENIED.

UNPUBLISHED

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, *Plaintiff,*	)
v.	) No. 93 CR 585
BALDEV RAJ BHUTANI, NEELAM BHUTANI, and ALRA LABORATORIES, INC., *Defendants.*	) John F. Grady,) *Judge*

ENTERED DECEMBER 29, 1994

ORDER

The defendant Baldev Raj Bhutani has filed a Renewed Motion to Set Aside Verdict.

The first ground of the motion is that the defendant has material, newly-discovered evidence. The evidence is that on the appeal of this court's order granting a new trial the prosecution argued that it had not contended at trial that the lactulose syrup was decomposed to the point that it was medically ineffective. Defendant argues that if this admission were brought to the attention of the jury in a new trial, the result of the second trial might well be different from the result in the first.

Statements made by a party during oral argument of an appeal in the case would be an unusual type of newly-discovered evidence, but it might well qualify if the defendant's basic premise could be accepted. That premise is that the prosecution did in fact contend at trial that the lactulose had decomposed to the point of ineffectiveness. In granting a new trial, we held that this had indeed been the government's position. However, the Court of Appeals found otherwise and held that we had been mistaken about what the tenor of the government's testimony and arguments at trial had been. In view of that, we are not free to find that statements made by the prosecution during oral argument of the appeal are materially different from the position it took at trial. We could grant the defendant's motion only by ignoring the decision of the Court of Appeals.

The second ground of the motion is that the jury instructions given failed to include the element of materiality required by the decision of the Supreme Court in the case of United States v. Neder, 119 S.Ct. 1827 (1999), decided after the trial. In Neder, the defendant was convicted under the federal mail, wire and bank fraud statutes. We agree with the government that Neder's materiality requirement does not apply to the statutes involved in this case.

The third ground of the defendant's motion is that the government knowingly offered perjured testimony of its witness James Ward. We considered Ward's testimony in connection with previous motions and find no reason to change our view that defendant is not entitled to a new trial on the basis of that testimony.

Accordingly, the renewed motion of the defendant Baldev Raj Bhutani to set aside the verdict is denied.

IN THE
SUPREME COURT OF THE UNITED STATES

No. 99-1120

BALDEV RAJ BHUTANI, NEELAM BHUTANI,
AND ALRA LABORATORIES, INC.
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Petition For Writ Of Certiorari To The
United States Court Of Appeals
For The Seventh Circuit

ENTERED FEBRUARY 22, 2000

Before REHNQUIST, STEVENS, O'CONNOR, SCALIA, KENNEDY, SOUTER, THOMAS, GINSBURG, and BREYER, *Supreme Court Judges.*

OPINION

Petition for writ of certiorari to the United States Court of Appeals for the Seventh Circuit denied.

UNPUBLISHED

IN THE
UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

ENTERED OCTOBER 4, 1999

Case Nos. 98-1154 and 98 CR 585

UNITED STATES OF AMERICA, *Plaintiff-Appellant,*	) Appeal from the) United States) District Court for) the Northern
v.	) District of Illinois,) Eastern Division.
BALDEV RAJ BHUTANI, NEELAM BHUTANI, and ALRA LABORATORIES, INC., *Defendants-Appellees.*	) **John F. Grady,**) ***Judge***

Before:

Hon. WILLIAM J. BAUER, Circuit Judge
Hon. KENNETH F. RIPPLE, Circuit Judge
Hon. TERENCE T. EVANS, Circuit Judge

Defendants-appellees filed a petition for rehearing and petition for rehearing en banc. No judge in regular active service has requested a vote on the petition for rehearing en banc, and all of the judges on the panel have voted to deny rehearing. The petition for rehearing is therefore DENIED.

IN THE
UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

No. 98-1154

UNITED STATES OF AMERICA,

Plaintiff-Appellant,

v.

BALDEV RAJ BHUTANI, NEELAM BHUTANI,
and ALRA LABORATORIES, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of Illinois, Eastern Division.
No. 93 CR 585-**John F. Grady, *Judge.***

ARGUED NOVEMBER 13, 1998
ENTERED APRIL 28, 1999

Before BAUER, RIPPLE, and EVANS, *Circuit Judges.*

BAUER, *Circuit Judge.* On February 12, 1996, after a ten week trial, a jury found the three defendants, Baldev Raj Bhutani, Neelam Bhutani, and ALRA Laboratories, Inc., guilty of a number of charges related to their manufacturing and distribution of mislabeled and/or adulterated generic pharmaceutical products. After various post-trial motions were denied, the defendants filed a motion for a new trial based on newly discovered evidence and/or the government's violation of *Brady v. Maryland*, 373 U.S. 83 (1963). The district court granted the defendants' motion for a new trial on all

counts of conviction based on the government's violation of *Brady*. The government now appeals that ruling. For the reasons set forth below, we reverse.

I. BACKGROUND

Baldev and Neelam Bhutani are the husband and wife team that owns ALRA Laboratories, Inc., a pharmaceutical company that produces generic prescription drugs. The trial primarily focused on the manufacturing and distribution process of two drugs produced by ALRA--Lactulose and K+10. Lactulose is a drug used to combat advanced liver disease, and K+10 is a potassium supplement.

On January 26, 1994, a federal grand jury filed a superseding indictment charging all three defendants with violations of 21 U.S.C. §§ 331(a), 331(e), 331(k), and 333(a)(2) and Baldev Raj Bhutani and ALRA with violations of 18 U.S.C. §§ 2, 371, 1001, and 1341. The indictment charged all three defendants with (1) adulterating and mislabeling their Lactulose products; (2) keeping improper records with respect to the Lactulose; (3) failing to meet the good manufacturing practice standards; and (4) introducing the adulterated Lactulose into interstate commerce--all with the intent to defraud and mislead. Additionally, all three defendants were charged with adulterating and failing to keep proper records with respect to their K+10 drug. Lastly, Baldev Raj Bhutani and ALRA were charged with provi[illegible]ng false statements to various divisions of the Food and Drug Administration ("FDA") and obtaining money through fraudulent schemes. While the trial delved into all of the charges against the defendants, this appeal relates only to a claim of the discovery of new, and the suppression of, evidence regarding the stability of Lactulose and the effect, if any, this had on the rest of the trial.

Lactulose is a drug that comes in a syrup form, much like the consistency of honey, that is used to treat the liver disease portal systemic encephalopathy. When an individual has this condition, the liver is unable to remove excess ammonia before it enters the bloodstream. Lactulose's function is to remove the ammonia from the colon and large intestine before it can enter the bloodstream. Lactulose is a disaccharide, meaning that it is a combination of two sugars. All drugs, including Lactulose, begin a degradation process after they are manufactured, which is why they are given expiration dates. As Lactulose ages, it breaks down into its component parts. Should it eventually decompose fully, a process that may take several years, then it would no longer be Lactulose, as the two sugars will have separated, rendering the drug ineffective. Only when the two sugars are combined may they act to remove ammonia from the colon and large intestine; neither sugar on its own can remove the ammonia. Without Lactulose, a person with portal systemic encephalopathy could slip into a coma caused by excess ammonia in the bloodstream.

One way of testing the stability of Lactulose is to measure its pH level. The pH scale measures the acidity or baseness of a chemical on a scale of 0 to 14. A chemical with a pH below 7 is an acid, while one with a pH above 7 is a base. At the time of the trial, the accepted pH range in which Lactulose was considered most effective, as set forth by the U.S. Pharmacopeia ("U.S.P."), also known as the "bible" of the pharmaceutical industry, was 3.0 to 7.0. The U.S.P. based this determination on stability data provided by various drug manufacturers to the FDA. As Lactulose ages and begins to degrade, it becomes more acidic, i.e. its pH drops. Thus, the older Lactulose gets, the lower its pH reading will become. If the pH level becomes too low, the drug will no longer be effective to fight the liver disease.

The main focus of that portion of the trial concerning ALRA's production of Lactulose centered around two separate lots of the drug: lots 52-230 and 52-231. At trial, the government claimed, and the jury found, that employees at ALRA, at the direction of Baldev Raj Bhutani, adulterated these lots of Lactulose by "spiking" them with the foreign substance sodium hydroxide in order to conceal their age. Sodium hydroxide is a base, and, when combined with a more acidic substance, will raise its pH level. The government introduced evidence that ALRA employees opened individual bottles of Lactulose from lots 52-230 and 52-231, spiked them with sodium hydroxide, re-sealed the bottles and re-packaged them for distribution with an erroneous expiration date.

Lots 52-230 and 52-231 were manufactured in June of 1986. However, ALRA did not obtain approval from the FDA until July of 1988 to distribute the drug. When ALRA finally received approval to market its Lactulose, it aimed to distribute these two lots of Lactulose by September of 1988. The government presented evidence at trial that lot 52-231 had a pH level of 4.6 in February of 1988 and a pH level of 6.6 in August of 1988. This change represents a 100-fold increase in pH (a chemical with a pH of 4.6 is 100 times more acidic than a chemical with a pH of 6.6). In addition, the government showed that lot 52-230's pH level increased from 4.7 to 5.1 over the same period of time. It was agreed at trial by both government and defense expert witnesses that there is no naturally occurring process which will increase the pH level of Lactulose over time.

Based on the evidence presented at trial, which consisted of expert testimony, testimony from employees of ALRA, and various data findings, on February 12, 1996, the jury found ALRA and Baldev Raj Bhutani guilty with respect to counts 3, 4, and 6 of the superseding indictment--charges relating to adulterating Lactulose, keeping inaccurate records, and

sending the adulterated drug into interstate commerce. In total, the jury found ALRA guilty on 8 of 13 counts, Baldev Raj Bhutani on 7 of 13 counts, and Neelam Bhutani on 4 of 10 counts.

On July 5, 1996, after filing various motions for post-trial relief, the defendants filed a motion for a new trial based on newly discovered evidence and/or a *Brady* violation. They claimed that the government, at the time of the trial, had in its possession stability data from numerous drug manufacturing companies that showed that the effective range for Lactulose was not in fact 3.0 to 7.0, and that Lactulose was still perfectly effective with a pH level as low as 2.5. Furthermore, they asserted that the U.S.P. released a proposal in May of 1996 to change the effective pH range for Lactulose from 3.0 to 7.0 to 2.5 to 6.5. The defendants argued that, under the standards set forth in *Brady*, the government was obligated to turn this information over to them. They further asserted that this new data completely undermines the government's theory of the case that the defendants were willing to put their own personal profits ahead of the safety of the public by putting adulterated drugs on the market. Additionally, they claimed that the government's theory had a prejudicial "spillover" effect in the jury's findings of guilty on all of the counts, even those counts unrelated to the production of Lactulose. Thus, they contend that all of the defendants are deserving of a new trial on all of their convictions.

The district court agreed with the defendants. The court stated that the government's prevailing theme throughout the case was the defendants' blatant disregard for public safety by shipping adulterated drugs into the marketplace just so they would not lose any profits by discarding the old, decomposed Lactulose lots. The court went on to say that since this new stability data showed that Lactulose was still effective at a lower pH level than the government represented at trial, the

data tends to show that the defendants would have less of a reason to be nervous about a pH level of 4.6, and, therefore, had no need to spike the product to raise its pH level. Thus, the court determined that the government's suppression of this new stability data "seriously undermines the court's confidence in the verdict of the jury on Counts 3, 4 and 6." *United States v. Bhutani,* WL 811689 at *14 (N.D. Ill. 1997). In addition, the court found that all of the counts of conviction were so entwined in the government's profit motive theory that it ordered a new trial for all defendants on all of their convictions, even those unrelated to the Lactulose charges. The government now appeals that ruling.

II. DISCUSSION

Appellate review of a district court's granting of a new trial in a criminal case is deferential. *United States v. Boyd,* 55 F.3d 239, 242 (7th Cir. 1995). However, when the review of a granting of a new trial based on a *Brady* violation revolves around a pure issue of law, our review is *de novo. United States v. Maloney,* 71 F.3d 645, 652-53 (7th Cir. 1995), *cert. denied,* __ U.S. __, 117 S. Ct. 295 (1996).

A. Brady Violation

Federal Rule 33 of Criminal Procedure allows a court to grant a defendant's motion for a new trial if it is required in the interest of justice. A motion for a new trial based on newly discovered evidence must be made within two years after final judgment. The district court granted the defendants' motion for a new trial because it found that the government did not fulfill its duties under *Brady* by not disclosing the stability data that was under the control of the FDA. We do not agree that the government committed a *Brady* violation.

Under Brady and its progeny, the government has an affirmative duty to disclose any evidence in its possession that is favorable to the defendant, and is material to either the issue of guilt or punishment. *United States v. Gonzalez*, 93 F.3d 311, 315 (7th Cir. 1996). Favorable evidence will be considered material if "its suppression undermines confidence in the outcome of the trial." *Id.* at 316 (quoting *United States v. Bagley*, 473 U.S. 667, 678 (1985)). The defendant does not have to show that it is more likely than not that the verdict would have been different if the evidence in question had been disclosed, but only that there is a "reasonable probability" that the outcome would have been different. *Gonzalez*, 93 F.3d at 316 (quoting *Kyles v. Whitley*, 514 U.S. 419,434 (1995)). Any nondisclosure of material exculpatory evidence by the government results in a violation of the defendant's due process rights.

Even though the government has an affirmative duty to disclose exculpatory evidence in its possession, it is not obligated to disclose "every possible shred of evidence that could conceivably benefit the defendant." *United States v. Hamilton*, 107 F.3d 499, 509 (7th Cir. 1997), *cert. denied*, __ U.S. __, 117 S. Ct. 2528 (1997). Nor does it have an obligation to turn over evidence of which it has no knowledge. *Id.* Moreover, the government cannot be found to have suppressed evidence if the same information was available to the defendant through the use of reasonable diligence. *United States v. Morris*, 80 F.3d 1151, 1170 (7th Cir. 1996), *cert. denied*, 519 U.S. 868 (1996).

While the government does not have the duty to disclose information of which it is unaware, if a government agency is charged with the administration of a statute and has consulted with the prosecution in the case, the agency will be considered part of the prosecution, and its knowledge of *Brady* material will be imputed to the prosecution. *See United States v. Wood*, 57 F.3d 733, 737 (9th Cir. 1995); *United States v. Anderson*, 1998

WL 991216 at *3 (D. Kan. 1998). "The government cannot with its right hand say it has nothing while its left hand holds what is of value." *Wood*, 57 F.3d at 737.

The material that the defendants claim was suppressed by the government is data that was in the possession of the FDA at the time of trial which said that Lactulose was perfectly stable and effective with a pH level as low as 2.5. Based on this evidence, the defendants claim that as early as late 1995, the U.S.P. planned to recommend a proposed change in the effective range of Lactulose syrup from 3.0 to 7.0 to 2.5 to 6.5. Therefore, the defendants contend that this information which was in the possession of the FDA was helpful to their case because, had they known of the proposed change, they would have informed the jury of the same and argued that the Lactulose was still effective when the alleged spiking incident occurred. The defendants claim that this evidence undermines the government's theory of the case since the defendants would have had no reason to spike the lots in question. As it turns out, the U.S.P. eventually published its proposal to change the effective pH range of Lactulose in May of 1996, three months after the jury's verdict.

While we agree with the defendants that information held by the FDA can, in this case, be imputed to the prosecution, we do not agree that the evidence in question is Brady material. Brady material must be (1) in the possession of the prosecution; (2) material; and (3) exculpatory. *United States v. Hartbarger*, 148 F.3d 777, 786 (7th Cir. 1998), *cert. denied*, __ U.S. __, 119 S. Ct. 1117 (1999). We disagree that the evidence in question was in the possession of the prosecution. The real evidence that the defendants rely on in their motion is the eventual publication of the U.S.P.'s proposal to lower the effective range of Lactulose. This was not published until well after the trial had ended. Simply because the FDA had stability data from other pharmaceutical companies does not

mean that they had any knowledge that the U.S.P. was going to recommend the proposed change in Lactulose's effective pH range. The government cannot be held responsible for failing to disclose merely speculative evidence. United *States v. Agurs*, 427 U.S. 97, 109 (1976), n. 16. Since we find that the evidence in question was not within the possession of the government, we need not decide whether it was exculpatory or material. Therefore, we disagree with the district court that the defendants should have been granted a new trial based on the government's alleged *Brady* violation.

B. Newly Discovered Evidence

Even though the evidence in question was not within the possession of the prosecution, the defendants may, nevertheless, be entitled to a new trial based on newly discovered evidence, an alternative theory raised in their motion for a new trial. The standard for determining whether a defendant is entitled to a new trial based on newly discovered evidence is different from that of determining whether one is entitled to a new trial because of a Brady violation. We have evolved a four part test to determine whether a defendant's motion for a new trial based on newly discovered evidence should be granted. The defendant must show that the evidence at issue (1) came to his knowledge only after the trial; (2) could not have been discovered sooner through the use of due diligence; (3) is material and not merely cumulative or impeaching; and (4) would probably lead to an acquittal in the event of a new trial. *Gonzalez*, 93 F.3d at 315.

The defendants argue that the U.S.P.'s recommendation to lower the effective range of Lactulose would have been helpful to their case because it would have destroyed the prosecution's profit-motive theory. They argue that since Lactulose does not lose any of its laxative effect and is still effective with a pH as low as 2.5, then there was no reason to spike the lots in

question. The district court agreed with them. We find that both the defendants and the district court mischaracterized the prosecution's argument.

The district court's decision relies heavily on the idea that the government portrayed the defendants as profit-hungry monsters who were willing to put the public's safety at risk in order to make a buck by putting ineffective drugs on the market. The court said that the government argued that the defendants spiked their Lactulose lots because they wanted to mask the fact that the product would soon be unfit for use. *Bhutani,* 1997 WL 811689 at *12 (N.D. Ill. 1997). Thus, the district court concluded that the new evidence undermines the government's profit-motive theory and the jury could very well have reached a different conclusion had it known of the new effective range.

We agree that the government's theory was that the defendants were driven by the desire to make a profit, but, after reviewing the trial transcript, we do not agree that the government's argument was premised on the fact that ALRA spiked the Lactulose lots because they would soon be unfit for use. In fact, the government did not argue that the Lactulose was unfit, or close to unfit. What the government did argue was that the defendants spiked the Lactulose lots because the lots were old and they wanted to conceal their age to make them look like newer lots of Lactulose produced by ALRA. The reason for this is that the FDA has determined that Lactulose should be marketed with an expiration date that is 18 months after its manufacture. Here, the lots in question were all manufactured in 1986 and not distributed until 1988. In order for the defendants to sell their product, it had to conform to FDA standards. Thus the defendants had to conceal the *age* of the product. They did this by raising the pH levels and marking the lots with expiration dates of September 1989. The government did not argue that the pH level in the

lots in question ever dropped below 3.0. In fact, when the government's expert witness, Dr. Hicks, was questioned by defense counsel, he stated that the pH levels were never outside of the effective range. Thus, it was the defense, and not the government, that put the effective range at issue in the first place. Neither Dr. Hicks, nor any other government witness, ever testified that the Lactulose in question was ineffective. The adulterated lots had the potential of becoming unsafe while in the marketplace with an inaccurate expiration date, but were not necessarily unsafe at the time of distribution. The government argued that the defendants put the public's safety at risk by supplying adulterated products, not necessarily ineffective ones.

Throughout the trial, the defendants contended that the spiking incident never occurred. However, based on all of the evidence, the jury simply believed the prosecution's case over the defendants'. The Prosecution presented expert witnesses who testified that there is no naturally occurring process which can reverse the trend of Lactulose's degradation. In addition, the government called former employees who participated in the spiking incident to describe the process that was used in adding the sodium hydroxide to the Lactulose syrup. Those employees described, in detail, the "assembly line" type procedure that was used in opening the Lactulose bottles, injecting them with sodium hydroxide with a turkey baster type instrument and later a syringe, re-sealing the bottles, and repackaging them with falsified expiration dates. The government also presented employee time cards with extensive overtime recorded on the days the spiking incident occurred. Lastly, these employees testified that Baldev Raj Bhutani oversaw and authorized the entire operation. The defense had ample opportunity to cross examine these witnesses, and indeed they did. The fact that the U.S.P. subsequently proposed a lower effective pH range for Lactulose is of no consequence to the case since the government never argued

that the Lactulose's pH was outside of the effective range, or even close to being outside the range.

The trial judge properly instructed the jury on what it must unanimously find in order to convict the defendants on counts 3, 4, and 6. Count 4 charged that the defendants, with the intent to defraud and mislead, failed to establish and maintain accurate drug manufacturing batch production records for the Lactulose lots in question. In order to find the defendants guilty, of this count, the jury had to unanimously find that the defendants injected the lots with sodium hydroxide. The jury unanimously found this with respect to Baldev Raj Bhutani and ALRA, but not Neelam Bhutani. For count 3, the jury had to find that the lots of Lactulose were adulterated. The judge instructed the jury that the drug could have been adulterated in one of three ways. First, it could have been produced in a way that did not conform with the good manufacturing practices. Second, it could have decomposed to such a point that it no longer met applicable testing specifications. Third, the defendants could have added sodium hydroxide to it. The jury only had to find that any one of those three events occurred for the drug to be adulterated. The same is true for count 6.

Arguably, the new proposal by the U.S.P. could have shown that the Lactulose still met specifications even though it had degraded some. However, since the jury found in count 4 that the defendants added sodium hydroxide to the Lactulose, then it implicitly found that the drug had been adulterated with respect to counts 3 and 6 as well. Its finding in count 4 acts as an independent basis of a finding of adulteration for counts 3 and 6. Therefore, while the new data could show that the Lactulose had not degraded to the point of making it unsafe, the jury nonetheless found that the drug was adulterated by the addition of sodium hydroxide. Thus, the

defendants are not entitled to a new trial for counts 3, 4, and 6 based on newly discovered evidence.

C. The Spillover Effect

Lastly, the district court ruled that all of the defendants were entitled to a new trial on all of their convictions, even those unrelated to Lactulose, because all of the charges were so entwined with the government's profit-motive theory that it influenced the jury's decision on the other counts. Since we have determined that the defendants are not entitled to a new trial for counts 3, 4, and 6 because of the new evidence, it necessarily follows that there could be no spillover effect on the other counts. Even if we were to find that the defendants were entitled to a new trial for the Lactulose charges, the other convictions were based on an entirely different set of facts and conduct for a different drug altogether. These convictions were based on the manufacturing of K+10 and how a foreign substance was accidentally introduced into the mixing process, yet the drug entered the marketplace regardless. Even if the new evidence would have led to a different outcome in counts 3, 4, and 6, the new evidence has absolutely no relation to the conduct for which the defendants were found guilty in the manufacturing and record keeping of K+10. These violations contain completely different elements and are not related to the U.S.P.'s new proposal whatsoever. The jury found beyond a reasonable doubt that the defendants were guilty of these counts regardless of the Lactulose charges as evidenced by the fact that it did not find that Neelam Bhutani was guilty of counts 3, 4, and 6, but that she was guilty for her role with respect to the K+10 offenses. Therefore, the defendants are not entitled to a new trial on these additional counts.

III. CONCLUSION

For the reasons set forth above, we REVERSE the district court's ruling that the defendants are entitled to a new trial on all of their convictions based on a *Brady* violation or newly discovered evidence and REMAND to the district court with orders to reinstate the verdicts of conviction and to sentence the defendants to appropriate terms as prescribed by the Sentencing Guidelines.

A true Copy:

Teste:

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Clerk of the United States Court Of Appeals for the Seventh Circuit

UNPUBLISHED

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, *Plaintiff,*	)	
v.	)	No. 93 CR 585
BALDEV RAJ BHUTANI, NEELAM BHUTANI, and ALRA LABORATORIES, INC., *Defendants.*	)	

ENTERED DECEMBER 16, 1997

MEMORANDUM OPINION

Pending before the court is "the Motion of the Defendants for a New Trial Based on Newly Discovered Evidence and/or Violation of Brady v. Maryland." The motion will be allowed, for the reasons explained in this opinion.

Procedure

The defendants in this case are Baldev Raj Bhutani, Neelam Bhutani, and ALRA Laboratories, Inc., a corporation Baldev and Neelam Bhutani own and operate. ALRA is in the business of manufacturing and distributing generic drug products. The indictment included allegations that the defendants conspired to commit and did commit certain offenses involving adulteration and misbranding of various

drug products. The counts of the indictment that are primarily involved in the pending motion for a new trial are Counts 3, 4 and 6. The gist of these counts is that the defendants fraudulently adulterated quantities of Lactulose Syrup by adding an "undocumented substance," namely, Sodium Hydroxide. The jury found ALRA and Baldev Bhutani guilty on these three counts and was unable to reach a verdict as to Neelam Bhutani. [1]

Lactulose Syrup is used for the treatment of a serious liver disease known as portal systemic encephalopathy. This condition, caused by liver failure, results in ammonia reaching the bloodstream and the brain rather than being excreted. It can cause hepatic coma or death. Lactulose Syrup "reduces the absorption of the ammonia from the colon and thereby decreases the load that goes to the poor old liver that's injured and can't handle it. So that less ammonia is going to get to the blood that goes to the brain." In this way, the Lactulose "prevents [portal systemic encephalopathy] if it hasn't happened and it reduces it if it's already there."[2]

Lactulose is a "disaccharide," or a combination of two sugars, and it must reach the colon in that form if it is to absorb the ammonia and do its laxative work. It is important, therefore, that Lactulose ingested by a patient not be broken down, or degraded, into its separate components. If it is, it

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[1] Neelam Bhutani, therefore, would have a new trial on these counts in any event, but she argues that because of the newly discovered evidence, there is a Aspillover effect@ which entitles her to a new trial, as well, in regard to the other counts on which she was found guilty. This argument is addressed at pp. 28-30, infra.

[2] Testimony of Dr. John Senior, pp. 26-27.

will be absorbed in the small intestine and never reach the colon.[3]

Lactulose which is in its optimal, disaccharide condition is said to be "stable." A way of testing the stability of the solution is to determine its "pH" level, that is, its point on the range between acid and base. The scale runs from 0 to 14, with 7 being considered neutral. The lower the pH, the more acidic the solution will be. At some level, a pH reading will be so low as to indicate a breakdown of the Lactulose into its constituent monosaccharides. According to the testimony of Dr. Hicks, Lactulose is "optimally stable at somewhere between a pH of 4 to 5."[4]

The government's contention at trial was that defendants' Lactulose lots in question were old and had become unstable or dangerously close to being unstable, so that they were either medically ineffective or close to becoming medically ineffective. It was for this reason, according to the government, that defendants injected these aged Lactulose lots with Sodium Hydroxide, a base, in order to raise the pH of the Lactulose and make it appear safe for use. Adding pH to decomposed Lactulose would not, of course, restore it to its disaccharide form; it would merely mask the fact that the decomposition had occurred.

The motive was profit, said the government. The defendants did not wish to discard the decomposed Lactulose, so they disguised it in order to make it saleable. This theme of cutting corners and making profits in disregard of public health was emphasized to the jury as early as the prosecutor's opening statement:

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[3] Testimony of Kevin Hicks, p. 34.

[4] Id., p. 34.

This is a case about a pharmaceutical company that put contaminated drug products on the market and lied to the Food and Drug Administration about it. It is about the decisions of the company's president and a company's quality control director to violate the rules governing the pharmaceutical industry. It is about their decisions to cut corners in the manufacturing and in the testing of human pharmaceuticals and to put adulterated and misbranded prescription drug products on the market.

Why? To make money. Because cutting corners saved money and selling defective products raised their own profits. This case is about a corporation and its two officers' repeated decisions to put their personal profit ahead of the public health, and their decisions to line their own pockets instead of ensuring that patients, their customers, were receiving safe and effective prescription medication.

* * *

Again, why did they do this? To make money. This case is about a corporation and its officers' repeated decisions to put money over the quality of their product, to line their own pockets instead of ensuring that their customers were taking safe and effective medicine and to put their private profit over the public health.

* * *

Now through the next few weeks, the government will not attempt to review with you everything that happened to ALRA over a five-year period. We won't tell you what happened each and every day. But what we will do is we will bring witnesses before you, former employees of Alra, who will tell you about some of the things that went wrong at the firm. We will tell you what happened on those occasions when Baldev Raj Bhutani and Neelam Bhutani chose to break the rules and when they directed their employees-to ignore . the ANDA [ABBREVIATED NEW DRUG APPLICATION] procedures and violate the CGMP [CURRENT GOOD MANUFACTURING PRACTICES] regulations and when they allowed defective products to enter the market.

Over the next few weeks we will present to you six incidents, and the incidents document what went wrong at the firm, what violations occurred.

The first incident that you will hear about involves a drug product called Lactulose, and Lactulose is a prescription drug. It is a liquid and it comes in 8 and 16 ounce bottles and is used for patients who have a disease called portal systemic encephalopathy. And it is essentially people who have extensive liver disease or liver failure. And the product is used to draw contaminants out of the body and to prevent coma. That is what it says on the label.

* * *

That is not all they did. Before they shipped the product out the door, they took another important step to cover up the fact that they were shipping expired product. Oftentimes large buyers or wholesalers of generic drug products will test a product once it has been received, and they will test a product like Lactulose for something like pH or acidity, and these tests are designed to assure that the product is not degrading, that it is still within specification.

Baldev Raj Bhutani and Neelam Bhutani knew this. In fact, ALRA was selling these products to large pharmaceutical wholesalers including the AARP and Biolab.

So what do the Bhutanis do? The defendants instructed their employees to open up the bottles of Lactulose, those 1986 bottles, and inject a chemical called sodium hydroxide into the bottles in order to raise the pH and make it appear that the product had not, in fact, degraded.

They added this undocumented component through an unapproved procedure to mask or to hide the underlying degradation of the product. So even when a diligent consumer like a wholesaler might test a product, they could not know that the product had degraded, and the expiration date the defendants had put on the label was a lie. The defendants chose to label a product with an expiration date more than three years after its date of manufacture even though they knew the product was only

approved for 18 months. They injected a chemical into the product to mask the fact that the product had degraded.

Why? Because destroying the product would cost money, and selling the expired product would make money. Now, that is what the government will show you with respect to this first incident, and you will see proof in documents and you will hear the evidence through the testimony of witnesses.

You will first hear from Dr. Kevin Hicks, and he is the carbohydrate chemist. He is an expert on Lactulose, and he will tell you that Lactulose is a type of carbohydrate called a disaccharide, and this disaccharide degrades over time. And as time passes, the product breaks down into its component parts. And you can detect this degradation of the product by testing its pH. And as the product degrades, the pH will decrease.

And Dr. Hicks will tell you that adding the chemical, sodium hydroxide, before shipping a product out would simply mask or hide the degradation. It would not reverse it. It would not make the product new again.

In addition, another expert, Dr. John Senior, the gastroenterologist, will tell you that he treated hundreds of patients with this disease of portal systemic encephalopathy, the liver failure, and that he prescribes Lactulose to treat patients. He will tell you that if a product is sufficiently old and the disaccharide has

> degraded in to its component products, the Lactulose simply will not work. The drug will be ineffective in treating the patient's advanced liver disease. And a physician may have to resort to other measures to prevent coma.[5]

At trial, the government called a number of former ALRA employees who testified that at the direction of the Bhutanis, they injected sodium hydroxide into bottles of Lactulose Syrup, using syringes. The Bhutanis denied on the witness stand that any such thing occurred.

On the question of whether the Lactulose in question was likely to have been medically ineffective at the time it was shipped, the government elicited the following testimony from Dr. Senior:

> Q. Does the Lactulose have to be in the disaccharide form in order to work?
>
> A. Of course. If it's not in the disaccharide form it's not Lactulose.
>
> Q. If Lactulose is degraded into monosaccharide components, would it work to treat portal systemic encephalopathy?
>
> A. No, it won't work if it's degraded or split because the split products of Lactulose are fructose and galactose, which are easily-absorbed sugars. They're gone; they never get to the colon.

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[5] Smolover Opening Statement, pp. 4-5, 12-14, 16-17, 20-21.

Q. So, if the Lactulose has been split before you give it, it will not reach the colon.

A. Well, of course. I mean, if the Lactulose is effective it is Lactulose. If it's not Lactulose, then it doesn't work.

Q. Conversely then, would Lactulose be less effective if it had broken down, or a substantial portion had been broken down?

A. Of course it would be less effective if it had been broken down. Of course.

Q. Would lactulose, if it had degraded into its component parts, be effective in treating portal systemic encephalopathy?

A. No, it would not.

Q. Why would that be?

A. Because the degraded products would not reach the colon; they would be absorbed by the small intestine before the material reached the colon. So the bacteria in the colon would have nothing to work on. So they could not acidify, they could not cause a laxative effect.

Q. And would a physician be able to ascertain what was wrong if Lactulose had broken down intoits disaccharide form?

A. That makes it very hard on the physician, because a lot is going on in these sick patients. They have got a failing liver, they

> often have -- they are now getting failure of the brain function, they often have kidney failure that goes with the liver failure. They've got a lot of problems. And the last thing a physician is going to think of when he prescribes a drug is it isn't what it's supposed to be. That's not something that would occur to a physician right away. He would not quite know what to do if it wasn't working.[6]

The prosecutor in her closing argument drove home to the jury this testimony of Dr. Senior as demonstrating the dangerousness of the Lactulose that had been injected with the Sodium Hydroxide:

> Now, after you heard about all the chemistry, you heard from a physician, and that was Dr. John Senior. And he told you the medical consequences of this degradation and why in very human terms, this all matters.
>
> Dr. Senior was that gastroenterologist who has practiced for 30 years. And he explained to you that Lactulose is used to treat a condition called portal systemic encephalopathy. It's basically a condition resulting from serious liver disease. And he told you about his experience treating 3,500 patients.
>
> He explained to you that in patients with this condition in their livers, their liver stops to function because the liver cannot remove the ammonium from the blood; and, without intervention, the ammonium in the blood

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[6] Testimony of Dr. John Senior, pp. 27-29.

reaches the brain, compromises brain function and can cause coma and sometimes death.

Lactulose is used to substitute for a healthy liver. Lactulose works in the colon, the large intestine, to bind with the ammonium and excrete it before it can enter the bloodstream.

But as Dr. Senior pointed out, the Lactulose has to reach the large intestine in order for it to work. If the Lactulose is already broken down, if it is already degraded into its monosaccharide form, the monosaccharides will be absorbed in the small intestine, they'll be digested, and the Lactulose in its disaccharide form will never reach the colon, the site of the therapeutic treatment. And it will be rendered ineffective in treating patients with hepatic coma or portal systemic encephalopathy.

And Dr. Senior told you that a physician would not surmise that something was wrong with the Lactulose. They'd be forced to switch to another therapy, another treatment, that could potentially pose more risk.

And Dr. Senior pointed out that the less concentrated the Lactulose, the less disaccharide form of the Lactulose in that bottle, the less effective it's going to be in treating the disease condition for which it should be used: portal systemic encephalopathy.

Now, you've heard all this evidence about the reworking of the batches. You have heard

all these -- witness after witness tell you about the sodium hydroxide injection. You've heard about the labeling of September '89, where that date came from and how it was put on the bottles.

And we've talked to you about the motive in committing these crimes. The lots were reworked because the defendants didn't want to lose money and throw these expired lots away. They injected the chemical to mask the degradation, so the consumer would not know that the product has degraded.

They failed to document the rework in the batch records, so that the FDA, when examining the records, wouldn't know what had happened.

And they put a label on the product that was more than three years after the date of manufacture, even though they knew that the appropriate expiration date at any time was not more than 18 months.

And they did so to raise money, because destroying that old product would cost them money and selling expired product would raise profits.[7]

The government's "Version of the Offense" which the prosecutors submitted to the probation officer for inclusion in the presentence report shows that the government believed it

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[7] Smolover closing, pp. 40-42.

had proved the defendants had injected the sodium hydroxide to conceal the medial ineffectiveness of the Lactulose:

> The expert testimony of a carbohydrate chemist and gastroenterologist at trial indicated that these lots posed a risk to the public health, as degraded Lactulose will not be effective in treating portal systemic encephalopathy. Left untreated the condition can be life threatening.[8]

The government went on to state its position that the defendants should receive a 2 point enhancement under sentencing Guideline 2Fl.1(b)(4) because the offense "involved the conscious risk of serious bodily injury:"

> The Government's gastroenterology expert testified that Lactulose is used to treat a condition called portal systemic encephalopathy, caused by advance liver failure. The Lactulose must reach the colon in its original disaccharide form in order to bond with ammonium and rid the system of this toxin. If the Lactulose has degraded it will break into monosaccharides and be absorbed in the small intestine. It will not reach the colon at all. The ammonium, in turn, will remain in the blood, reach the brain, and may cause hepatic coma or even death. The expert further testified that a physician treating a patient with this condition is unlikely to presume that the Lactulose is defective. The doctor is thus likely to employ more radical drug therapy in attempting to

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[8] Government's Version of the Offense submitted as to the defendant ALRA, dated April 22, 1996, p. 9. (Identical statements were submitted for the two individual defendants).

> treat the portal systemic encephalopathy and resulting coma. Finally, the defendant's own chemistry expert testified that the injection of sodium hydroxide itself can pose significant risk to those consuming the product and the chemical may exist in a concentrated form in pockets of the liquid and may be lethal.[9]

The Pretrial Discovery

Extensive pretrial discovery motions were filed by the defendants. The court had the impression from the government's representations that it was furnishing everything the defendants were entitled to, and more. At one point the government filed a response stating that

> [f]or over fifteen months, the government has complied with, and far exceeded, its discovery obligations under Rule 16 of the Federal Rules of Criminal Procedure and Local Rule 2.04. The government promptly turned over all Brady material and provided the Defense with access to and copies of, all records in the possession of government counsel to which the Defense was even remotely entitled.[10]

The Response went on to state that

> (a]ll Brady (i.e., potentially exculpatory) material has been produced. In making its Brady production, the government has taken a very expansive approach and produced any materials that are simply "favorable" to the

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[9] Id. at 16-17.

[10] Government Collective Response filed August 23, 1995, at 2.

> Defense, even if not 'exculpatory.' Of course, the government recognizes its continuing obligation under Brady and will produce any additional materials of which the government becomes aware.[11]

THE DEFENDANTS' MOTION

The evidence at trial was that the pH range recommended for Lactulose by the U.S. Pharmacopeia ('U.S.P.') was between 3.O and 7.0. The recommendation by the U.S.P. is based on stability data made available to it by drug manufacturers. The same data is submitted by the manufacturers to the U.S. Food and Drug Administration, the agency which investigated this case and worked closely with the Department of Justice throughout its prosecution.

The verdict of the jury was returned on February 12, 1996. In June of 1996, the U.S.P. issued a bulletin that proposed revision of the pH range downward from 3.0-7.0 to 2.5-6.5. The explanation given by U.S.P. for the proposed change was that:

> Based on information received that stability data has shown a downward trend in pH over time, it is proposed to revise the pH range in this monograph. The proposed pH range is reported not to have any significant impact on the safety and quality of this product: it does not in any way effect the laxative properties of the product, and it does not affect the level of the related substances.

Based on this information, the defendants filed the present motion, contending that the stability information should have

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[11] Id. at 9.

been disclosed to the defendants inasmuch it undercut the government's contention that the Lactulose involved in Counts 3, 4, and 6 was at or near the point of medical in-effectiveness at the time it was distributed by the defendants:

> Specifically, it was alleged and repeatedly argued that, because the pH of the lactulose syrup that had been manufactured in 1986 was dropping close to a level 3, such lactulose was in fact decomposed and thus, the therapeutic effects of the lactulose were being lost and the health of consumers was therefore jeopardized. It was the Government's position that, as the pH dropped below 3, certain portions of the lactulose or its parts were being dissipated to impact quality. Thus, it was theorized that if a patient was not responding well to lactulose treatment, a physician had no way of knowing whether it was from the patient's condition or whether the lactulose was no longer effective.
>
> Accordingly, the Government's thrust was not merely to demonstrate that sodium hydroxide, an approved additive, was added to the lactulose in 1988, but to prove that the addition of sodium hydroxide was to mask lactulose decomposition, thereby endangering the lives and safety of the consumer simply to profit the Defendants. However, recently discovered evidence not only provides significant support for the Defendants' position that the lactulose was safe, but also demonstrates that the Government knew it was safe and still argued the contrary to the jury and this Court.[12]

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[12] Memorandum in Support of Motion for New Trial Based

The motion has been pending for a considerable period of time, due in part to the fact that, over the government's objection, the court allowed the defendants' discovery in connection with the motion and required the government to produce the stability records filed with the FDA by the Lactulose producers for the years underlying the U.S.P. proposal. These stability records do indeed support the proposal and demonstrate that Lactulose with a pH as low as 2.5 is stable and medically effective. The government does not contend otherwise, nor does it even contend that the FDA was unaware of the contents and significance of these records prior to trial. However, it makes a variety of arguments as to why, as a matter of law, the defendants are not entitled to a new trial.

THE LEGAL ARGUMENTS

Defendants have moved for relief under Brady v. Maryland and Rule 33 of the Federal Rules of Criminal Procedure. The parties have not specifically addressed the question of which test applies in the event there are any differences between Rule 33 and Brady. The defendants rely mainly on cases decided under Brady, while the government's emphasis is largely on cases decided under Rule 33. There is a difference between the two approaches, and it will be useful to point out that difference before proceeding to a discussion of the parties' arguments.

Federal Rule of Criminal Procedure 33 permits a defendant to request a new trial based on "newly discovered evidence." See Fed. R. Crim. P. 33 (stating that "[a] motion for a new trial based on the ground of newly discovered evidence" may be

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on Newly Discovered Evidence and/or in Violation of Brady v. Maryland, pp. 1-2.

made before or within two years after final judgment). In most cases, a defendant making such a request "must satisfy a stringent multi-stage test." United States v. Gootee, 34 F.3d 475, 479 (7th Cir. 1994). The defendant must show that the evidence in question (1) came to his knowledge only after trial; (2) could not have been discovered sooner through the exercise of due diligence; (3) is material and not merely impeaching or cumulative; and (4) would probably lead to an acquittal in the event of a new trial. United States v. Gonzalez, 93 F.3d 311, 315 (7th Cir. 1996); United States v. Severson, 49 F.3d 268, 271 (7th Cir. 1995); United States v. Young, 20 F.3d 758, 763 (7th Cir. 1994). This multi-part test is also known as the "Berry rule," since it was first articulated in a state court case of the same name over 100 years ago. 3 Charles Alan Wright, Federal Practice and Procedure § 557, at 315 (2d ed. 1982 & Supp. 1997) (citing the 1851 Georgia case of Berry v. State).

Significantly, however, the Berry rule applies only to "ordinary" motions for new trials based on claims of newly discovered evidence. Id., at 316. Different, less restrictive rules apply if a motion for a new trial is based on a claim of nondisclosure or suppression of evidence by the prosecution. Id.; See also id., § 557.2, at 352-53 ("[A] situation in which it is clear that the Berry rule does not apply is where the government has failed to disclose evidence favorable to the defense."). As a result, a Rule 33 motion containing a "suppressed evidence" claim is governed by the standards set forth in Brady v. Maryland, 373 U.S. 83 (1963), and its progeny. See United States v. Kelly, 790 F.2d 130, 133 (D.C. Cir. 1986) (specifically acknowledging that the Berry rule "does not . . . govern motions f or a new trial when the newly-discovered evidence indicates that the original trial was marred by a sixth amendment or Brady violation"). Most federal cases do not expressly discuss the difference between "ordinary" Rule 33 motions and Rule 33 motions based on Brady, but the cases at least implicitly recognize the distinction by applying Brady in

lieu of the Berry rule. See, e.g., Gonzalez, 93 F.3d at 315-16; United States v. Veras, 51 F.3d 1365, 1374-75 (7th Cir.), cert. denied,, 116 S. Ct. 540 (1995) ; Young, 20 F. 3d at 764; See also, e.g., United States v. Wong, 78 F.3d 73, 79 (2d Cir. 1996); United States v. Thornton, 1 F.3d 149, 158 (3d Cir. 1993); United States v. Stephens, 964 F.2d 424, 435-36 (5th Cir. 1992).

The criteria for relief under Brady are as follows. A defendant must establish that (1) the prosecution suppressed evidence; (2) the evidence was favorable to the defense; and (3) the evidence was material to an issue at trial. United States v. Morris, 80 F.3d 1151, 1169 (7th Cir.), cert. denied, 117 S. Ct. 181 (1996); United States v. Payne, 102 F.3d 289, 293 (7th Cir. 1996) (both citing United States v. Silval, 71 F.3d 667, 670 (7th Cir. 1995)). Evidence is considered "material"

> if there is a reasonable probability that the disclosure of that evidence to the defense would have changed the result of the trial. There is a reasonable probability of a changed result where the government's suppression of evidence "undermines confidence in the outcome of the trial."

Payne, 102 F.3d at 293 (quoting Kyles v. Whitley, 115 S. Ct. 1555, 1556 (1995) and United States v. Bagley, 473 U.S. 667, 678 (1985)); see also United States. v. Hamilton, 107 F.3d 499, 509 (7th Cir.), cert. denied, 117 S. Ct. 2528 (1997); Gonzalez, 93 F.3d at 316; United States v. Maloney, 71 F.3d 645, 653 (7th Cir. 1995), cert. denied, 117 S. Ct. 295 (1996) (each reiterating that evidence is material if its suppression undermines confidence in the outcome of the trial).

The Government's Arguments Based on the Four-Part Test

Relying on cases decided under Rule 33, the government argues that defendants' motion fails each part of the four-part test required under that rule. As noted above, Brady, rather than Rule 33, provides the requirements defendants must meet, and this makes a difference which is immediately apparent. The government initially argues that because the defendants knew prior to trial that their competitors had submitted stability data to the FDA, they fail the first part of the Rule 33 test. The government contends that it is not what the data shows, but rather that the data had been submitted to the FDA, which is important for Rule 33 purposes.

We would not be persuaded by this argument even if Rule 33 provided the governing test, because we think the relevant fact is not that the stability data had been submitted to the FDA, but that the data contained information indicating that Lactulose with a pH level as low as 2.5 was entirely stable and effective. But Brady, not Rule 33, applies to the situation, and the government's argument clearly does not fit a Brady analysis. As we shall see, the stability data in the possession of the government threw substantial doubt on its theory of the case and was therefore evidence favorable to the defense. The fact that the defendants knew stability data had been submitted to the government, without knowing what it showed -- and without any easy means of obtaining this proprietary information -- is irrelevant. There is no suggestion that the defendants knew or even had any reason to suspect prior to trial that the stability records contained information favorable to them.

Next, the government argues that the defendants failed to use due diligence to discover the stability information prior to trial. This second part of the Rule 33 test is not part of a Brady analysis, so it need not detain us long. The government sees

no reason why the defendants did not seek the stability information from the competitors or from the FDA prior to trial, even though they had no way of knowing the effort would produce evidence favorable to them. It would not have been a simple matter, nor can the court say at this time how it would have ruled had discovery motions been made. It is likely the competitors would have objected on the basis of the proprietary nature of the information, and the court probably would have applied a balancing test. This could have resulted in a finding that the probability of favorable evidence was too speculative to justify the intrusion. As far as the FDA itself is concerned, the government strenuously objected to the defendants' motion to produce the stability records even after the U.S.P. disclosure of what the records showed and the present motion had been filed by the defendants. The government argued that the work involved in locating and producing the records would be an enormous and unnecessary burden.

Even if the Rule 33 "due diligence" test applied, therefore, we believe it would not require the defendants to have undertaken pretrial discovery motions to obtain the competitors' stability data. It is by no means clear that, had they done so, they would have been successful.

In any event, the government cannot reasonably argue that defendants failed to do anything they needed to do in order to satisfy Brady. They moved repeatedly for production of Brady materials and both they and the court were assured by the government that all such materials would be produced, both those that were "exculpatory," and those which were "favorable" to the defense.[13] The defendants had a right to rely upon the government's obligation to produce favorable evidence even without such an assurance, but certainly with

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[13] See p. [14a], supra.

the assurance it was reasonable for the defendants to believe that no favorable evidence was being withheld.

The third part of the test under Rule 33 is that the newly discovered evidence must be "material and not merely impeaching or cumulative." The government has a variety of arguments as to why the stability data would have been irrelevant, confusing, and generally inadmissible. It contends, for one thing, that the evidence would have resulted in 'mini-trials' concerning the comparability of the various competitors' manufacturing processes and testing methods to those of ALRA to determine whether the competitors' results supporting the 2.5 pH level would be indicative of the safety of ALRA's Lactulose at the same level. In a curious begging of the question, the government argues that a major distinguishing feature of ALRA's Lactulose is that it had been injected with sodium hydroxide, as alleged in Counts 3, 4 and 6.

This kind of argument puts the burden in the wrong place. It could be that the competitors' stability data would ultimately prove unpersuasive to the jury, or even turn out to be inadmissible. But there is no reason at this point to think that either of these things would be true. The government's case was presented without any suggestion that the various standards to which it sought to hold the defendants were not supported by relatively uniform manufacturing processes and testing methods throughout the industry. For the government now to suggest that the pH range shown to be safe for the rest of the industry is inapplicable to ALRA is a new position for which it has no evidence. The stability data is apparently favorable and certainly bears on a material issue. It is not cumulative of any other evidence, but instead contradicts the evidence in the case concerning the low end of the safe pH range for Lactulose.

The fourth part of the Rule 33 test is that the newly discovered evidence would "probably lead to an acquittal in the event of a new trial." How probable the acquittal must appear is not altogether clear under the cases, but that question need not be resolved because the test is different, or at least differently phrased, under Brady, and that is the test we will apply.

THE BRADY ANALYSIS

We now turn to the parties' arguments under Brady. The tests, it will be recalled, are that (1) the prosecution suppressed evidence; (2) the evidence was favorable to the defense; and (3) the evidence was material to an issue at trial.

Whether the Prosecution Suppressed Evidence

The government argues that it did not "suppress" favorable evidence because it did not know of the U.S.P. recommendation for a change in the pH range until after trial and, secondly, the defense could have obtained the stability data in the exercise of due diligence prior to trial.

There is some sleight of hand in the government's position. The primary favorable evidence is not the U.S.P. recommendation made in June of 1996, four months after the trial. The recommendation would probably be admissible at a new trial, and would undoubtedly be favorable to the defense. But the fact that the recommendation had not been made prior to the trial is irrelevant to the present motion. The favorable evidence that was suppressed is the stability data that was in the possession of the government for years prior to trial, which it does not deny it knew about and which it did not disclose to the defense. The failure to disclose this data satisfies the suppression requirement.

The second part of the government's argument concerning the suppression requirement switches to the stability data itself, rather than the U.S.P. recommendation or the competitors' application which prompted the recommendation, and suggests that the defendants could have obtained the data prior to trial. As we have already indicated. in the discussion of Rule 33, it is not clear the court would have ordered pretrial production of the data. But we need not decide that question in order to do the analysis under Brady, which imposes an affirmative obligation on the government to produce favorable evidence. United States v. Gonzalez, 93 F.3d 311, 315 (7th Cir. 1996); United States v. Payne, 102 F.3d 289, 293 (7th Cir. 1996). The government expressly recognized its obligation to do just that and the defendants were justified in relying on that assurance.

The first requirement under Brady, that the prosecution suppressed evidence, has been satisfied.

The second and third Brady requirements are that the evidence was favorable to the defense and that it was material to an issue at trial. The last requirement comes down to whether the government's suppression of the evidence "undermines confidence in the outcome of the trial." Payne, 102 F.3d at 293.

In this case, the question of whether the stability data was favorable to the defense and the question of whether its suppression undermines confidence in the outcome of the trial are closely related and it will be convenient to discuss them together. The court answers both questions in the affirmative, for the following reasons.

There is no reason to doubt that the stability data showing the safety and therapeutic effectiveness of Lactulose at a pH level as low as 2.5 would had been admissible at trial. The

government offered evidence of the 3.0 - 7.0 range, and certainly any data from the same manufacturers tending to support a lower range was relevant. In fact, had the stability data been made available, it is likely the government's presentation on the "dangerousness" issue, if made at all, would have been quite different than it was.

The government argues that a 2.5 level would have had nothing to do with the evidence in the case because there was no contention that the Lactulose involved in Counts 3, 4, and 6 ever dipped to a pH level that low. The test records of ALRA showed that the Lactulose in question at the time sodium hydroxide was allegedly injected into the bottles was approximately 4.6.

However, it was the government's contention that at the time of the injections the Lactulose had degraded to a point where, had its true pH been tested and determined by the purchasers, they would have learned that the product had degraded so far that it was or would soon be unfit for use. This explained the defendants' need to distort the true pH by adding sodium hydroxide that would elevate the pH reading and mask the decomposition of the product. This was the prosecutors' theme from the beginning to the end of the trial: to avoid losing profits on these decomposed Lactulose lots, the defendants manipulated their pH levels in order to make them appear saleable.

The court does not recall that the government conceded in its argument to the jury that ALRA's records as to the actual pH of the product prior to the alleged injection were accurate.[14]

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[14] Indeed, in one of its briefs filed in opposition to the present motion, on October 2, 1996, the government made this point:

> Second, based on the trial testimony of several witnesses, the laboratory testing conducted for and reported by the

In fact, it was a major contention of the government throughout the trial that ALRA's records were, generally speaking, unreliable.[15] But more than that, the government repeatedly emphasized that the naturally occurring process of degradation was continuous, so that even if the actual pH level was at 4.6 when the injections occurred, the jury still could have concluded that the defendants recognized the need for a "booster" before distribution in order to avoid detection of a real problem that would appear shortly after distribution. Had the jury known that, according to stability data from the very manufacturers whose records had been used to support the recommended range of 3.0 to 7.0, the level of 2.5 was shown

> not to have any significant impact on the safety and quality of this product: it does not in any way affect the laxative properties of the product, and it does not affect the level of the related substances,[16]

> Defendants was not reliable.... Accordingly, the fact that ALRA's pH test results for lots 52-230-P and 52-231-P were recorded as being within its specification was neither surprising nor probative.

Government's Memorandum on the Question of Whether the Jury was Misled in Regard to the Matter of Lactulose Degradation, p. 24.

[15] If the court recalls correctly, Rule 404(b) "other acts" evidence was admitted, over defendants' objection, to support the government's contention that much of what the defendants did in the operation of their business could not be accepted at face value.

[16] U.S.P. bulletin of June 1996 quoted in full at p. [16a] supra.

the jury could well have reached a different conclusion as to whether the defendants had a motive to jiggle the pH of their product. The level of 4.6 is not in the danger zone, and according to the competitors' stability data, the level of 2.5 was not in the danger zone. It is this fact -- that no problems of any kind had been reported at a 2.5 level -- that would have cast serious doubt on the government's motive theory. And, if the defendants had no motive to order their employees to engage in the cumbersome process of injecting sodium hydroxide into the Lactulose bottles, it is difficult to understand why they would have done it. The government obviously recognized how essential it was to prove a motive for behavior which, absent a plausible motive, would be inexplicable.

In short, the lower the safe pH level, the less reason the defendants would have had to be nervous about a level of 4.6 or anything in that area, and the less motive they would have had to do what is charged in Counts 3, 4, and 6.

Moreover, the testimony of Dr. Senior concerning the dire consequences of ineffective Lactulose would have had no purpose if the government was not contending that the Lactulose in question was dangerous. Nor would the emphasis on that testimony in the prosecutor's opening statement and closing argument have made any sense if the government was not arguing that the Lactulose was in fact dangerous.

The government attempts to avoid the consequence of its emphasis on the dangerousness of the Lactulose by pointing out that its argument to the jury was based in part on testimony that the injection of sodium hydroxide by itself rendered the product dangerous. This is another question-begging argument; it assumes the defendants did inject the Lactulose. We are concerned on this motion with the

suppression of evidence that went to the question of whether they did so.

There is another respect in which the stability data is material, quite aside from the question of motive. The evidence at trial was that testing of the lots in question had shown the pH level of the Lactulose to have increased for no apparent reason after the date of the alleged injections. The government's expert witness, Dr. Hicks, testified that the only explanation for this occurring in a closed container would be the addition of a base, such as sodium hydroxide. The defense expert, Dr. John Robyt, disagreed and said that the variations could be due to laboratory error. The government relied heavily on the testimony of Dr. Hicks in its final argument to the jury.

The competitors' stability data shows some variations in pH -- going up, back down and then up again - that are arguably similar to those shown in the ALRA records for the lots in question. The government argues that the increases in pH shown in the competitors' stability data are significantly lesser increases than those shown in the ALRA test data. Whether this is true or not is a somewhat complicated factual question, and one properly for the jury.[17] But even if it were true, it detracts little, if at all, from the materiality of the competitors' test data. Dr. Hicks testified that no increase could occur in a closed container without tampering. If the competitors' data show that any increases occurred in their laboratories, the data appears to contradict Dr. Hicks on this important question. Had the competitors' data been available to the jury, the defendants would have had support for their position that any unexplained variation in their own test

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[17] In its effort to distinguish the competitors' data, the government offers considerable factual information and analysis that is found neither in the data itself nor in the trial record.

results could have been due to laboratory error. There may be other or better arguments the defendants could have made.

The government argues that the evidence of the defendants guilt on Counts 3, 4 and 6 was so overwhelming that the competitors' stability data would have made no difference to the jury. This is not how the court remembers it. The description of the injection process given by the various employees who allegedly did it seemed unlikely in the extreme, unless there was some compelling motive for the defendants to have required them to engage in such a procedure. Not all of the employees who would have known about the incident agreed that it had occurred. Both of the Bhutanis denied that it had occurred. It seemed to the court at the time that the verdict could have gone either way, and, of course, there is no way of knowing how close the jury thought the question was. One thing that can be said for certain is that if the jury had entertained a reasonable doubt as to whether the defendants had a plausible motive for engaging in what otherwise would have been bizarre behavior, it could not have found the defendants guilty on Counts 3, 4 and 6.

The government's suppression of the evidence concerning the competitors' stability data seriously undermines the court's confidence in the verdict of the jury on Counts 3, 4 and 6. The court concludes that the defendants have satisfied the requirements of Brady v. Maryland and are entitled to a new trial on these counts.

The Spillover Question

The question remains whether the suppression of evidence specifically relating to Counts 3, 4 and 6 undermines confidence in jury's verdict on the other counts of conviction. The defendants argue that it does, inasmuch as the jury must have been affected in their consideration of the other counts by

their finding that the defendants, motivated by a desire for profit, sold defective Lactulose that would be used by unsuspecting patients for whom it would pose a risk of serious injury or death. The remaining counts of the indictment all charged the same kind of shoddy, unscrupulous behavior, motivated by desire for profit and indifference to public health. The government's description of these counts, and its explanation of why there was no prejudice that could have spilled over on to them, is wholly unpersuasive. Indeed, merely quoting the government's argument exposes the close connection among all the counts on which defendants were convicted and the consequent likelihood of a spillover effect:

> Moreover, the absence of competitors' stability data could have had no 'spill-over' effect on the other counts of conviction unrelated to Lactulose stability (i.e. counts relating to the leaking Lactulose Drums, the K+10 contaminated with a metal pipe, and the HITS training program, and the conspiracy which includes various recordkeeping deficiencies), as the jury found ample evidence on those counts.
>
> Finally, contrary to Defendants' claim, the jury's verdict was in no way tainted by the Government's theme (articulated in its opening statement and closing argument) that ALRA's modus operandi was to sacrifice the public health to make a profit. This theme was clearly borne out by the evidence relevant to the counts of conviction: selling Lactulose adulterated with sodium hydroxide injections (i.e., Count Three, Four, and Six); selling Lactulose from leaking drums (i.e., Counts Seven and Eight); selling K+10 with fragments of metal pipes ground up in it (i.e., Count Ten);

> and failing to employ trained technicians in manufacturing human pharmaceuticals (i.e., Count Fifteen).[18]

The court agrees with the defendants. All counts of conviction were entwined with the government's profit motive theory and its contention that the defendants would cut any corners they had to regardless of the consequences to public health. A finding that the defendants were so motivated could well have provided the basis for the jury's verdict on the other charges, each of which was vigorously contested. It is true that the defendants were found not guilty on some counts and that the jury failed to reach a verdict on others. Any effort to reconcile the different results would be entirely speculative, and it is impossible to conclude from those results that the Brady violation had nothing to do with the jury's conclusion on any count where guilt was found. The court has the same lack of confidence in the verdict on those counts as it does on Counts 3, 4 and 6.

CONCLUSION

Because of the government's violation of Brady v. Maryland, each of the defendants is granted a new trial on each count of conviction.

DATED: December 16, 1997

ENTER: _____

John F. Grady, United States District Judge

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[18] Government's Opposition to Defendants' Post-Trial Motion for a New Trial Based on Newly Discovered Lactulose Stability Evidence, filed June 16, 1997, pp. 39-40.

Supreme Court, U.S
FILED
MAY 17 2002
CLERK

(2)

No. 01-1188

In the Supreme Court of the United States

BALDEV RAJ BHUTANI, AND
ALRA LABORATORIES, INC., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

THEODORE B. OLSON
Solicitor General
Counsel of Record

ROBERT D. MCCALLUM, JR.
Assistant Attorney General

DOUGLAS N. LETTER
ROBERT M. LOEB
LAWRENCE G. MCDADE
Attorneys

Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

11 pp

QUESTIONS PRESENTED

1. Whether the district court committed reversible error in its instructions on proof of materiality under 21 U.S.C. 333(a)(2).

2. Whether petitioners' failure to maintain records as required by 21 U.S.C. 355(k) served as a valid basis for a conviction under 21 U.S.C. 333(a)(2).

3. Whether the district court's use of Sentencing Guidelines (Guidelines) § 2F1.1 violated the Ex Post Facto Clause.

4. Whether the evidence was sufficient to sustain petitioners' convictions for distributing contaminated Lactulose from leaking drums.

5. Whether the district court correctly determined that there was a fraud loss under Guidelines § 2F1.1.

6. Whether the court of appeals erred in determining that there was no inconsistency between the government's position on appeal and its position at trial.

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In the Supreme Court of the United States

No. 01-1188

BALDEV RAJ BHUTANI, AND
ALRA LABORATORIES, INC., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-15) is reported at 266 F.3d 661. The opinion of the district court (Pet. App. 18-19) is unreported. An earlier opinion of the court of appeals (Pet. App. 22-35) is reported at 175 F.3d 572. An earlier opinion of the district court (Pet. App. 36-66) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on September 12, 2001. A petition for rehearing was denied on November 14, 2001 (Pet. App. 17). The petition for a writ of certiorari was filed on February 12, 2002. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Following a jury trial in the United States District Court for the Northern District of Illinois, petitioners Bhutani and Alra Laboratories, Inc. were convicted of adulterating the drug Lactulose by adding sodium hydroxide (Count 3), failing to record the addition of the sodium hydroxide (Count 4), and distributing the adulterated Lactulose (Count 6). In addition, petitioners were convicted of distributing the drug "K+10" after it was contaminated with metal shards (Count 10), and using contaminated Lactulose concentrate as a drug ingredient and then selling the contaminated drug (Counts 7 and 8). Finally, petitioners were convicted of a conspiracy to commit the above substantive offenses (Count 1).

The district court granted petitioners' motion for a new trial. The court of appeals reversed and remanded for sentencing. The district court sentenced petitioner Bhutani to 30 months' imprisonment and fined both petitioners. The court of appeals affirmed.

2. Petitioner Bhutani is the owner of petitioner Alra Laboratories, Inc. (Alra), a pharmaceutical company. Pet. App. 23. Alra produces generic drugs, including Lactulose, a drug that combats liver disease, and K+10, a potassium supplement. *Ibid.*

The government's evidence at trial established that Bhutani directed his employees to spike two lots of Lactulose with sodium hydroxide in order to conceal the age of those lots. Pet. App. 25. In response to Bhutani's directions, employees opened bottles of Lactulose, spiked them with sodium hydroxide, resealed the bottles, and repackaged them for distribution with an erroneous expiration date. *Ibid.*

The government's evidence also established that an Alra worker dropped a metal pipe into a mixer containing a large batch of K+10. The pipe was then ground up into tiny pieces. After unsuccessfully attempting to remove the metal pieces, petitioners tableted the drug and released it for sale. Gov't C.A. Br. 8-9.

The government's evidence further showed that Alra received 36 drums of concentrated Lactulose that were dented, punctured, and leaking. Under Bhutani's directions, workers injected glue into the leaks and covered the leaks with duct tape. Although Bhutani told an insurance adjuster that the Lactulose concentrate was not fit for human consumption and would have to be destroyed, petitioners used the concentrate as a drug component and sold the contaminated drugs to the public. Gov't C.A. Br. 9.

3. After petitioners were convicted for their conduct, petitioners moved for a new trial, based on new evidence that Lactulose was effective with a pH as low as 2.5. Pet. App. 26. Petitioners asserted that the new evidence undermined the government's assertion that petitioners had a motive to spike the Lactulose, and that the spiking counts had a spillover effect on the other counts. The district court granted petitioners' motion. *Id.* at 36-66.

The court of appeals reversed. Pet. App. 22-35. The court first held that the government's failure to disclose the pH evidence did not violate *Brady* v. *Maryland*, 373 U.S. 83 (1963), because it did not come into the government's possession "until well after the trial had ended." Pet. App. 29. The court further held that the new evidence did not undermine the government's argument that petitioners had a motive to spike the Lactuolose. The court explained that the government never

claimed that petitioners spiked the Lactolose to mask the fact that the drug would soon become ineffective. *Id.* at 31. Instead, the government argued that petitioners spiked the Lactulose because the lots were old and petitioners wanted to conceal the age of the lots—an argument that was not undercut by evidence that the Lactulose was not close to becoming ineffective at the time it was spiked. *Ibid.* Finally, the court ruled that the new evidence had no bearing on petitioners' convictions on the counts that did not relate to the spiking of the Lactulose. *Id.* at 34.

4. On remand, petitioners once again moved for a new trial, claiming that the government's position on appeal contradicted its theory at trial. The district court denied the motion, holding that the court of appeals had already concluded that there was no inconsistency. Pet. App. 18-19. The district court also rejected petitioners' contention that the jury instructions were defective because they failed to require the jury to find materiality as an element of an FDCA violation. *Id.* at 19.

The court of appeals affirmed. Pet. App. 1-15. The court first rejected petitioners' contention that the government's position on appeal contradicted its trial theory. The court explained that "[a] second read of the trial transcripts reveals that the government's position at trial and on appeal has been consistent." *Id.* at 2. In particular, "[t]he government did not show at trial that the [old] Lactulose was outside the accepted pH range or medically ineffective; rather it admitted that the pH was at all times within range, but that it was dropping, which signaled degradation, and in order to mask any degradation the defendants raised the pH by adding sodium hydroxide so that the fact that it was being sold

past its expiration date could not be detected." *Id.* at 2-3.

The court of appeals also rejected petitioners' contention that, because of a drafting error during a 1984 recodification, it was not a crime under 21 U.S.C. 331(e) for petitioners to alter their records with the intent to defraud or mislead. The court held that Congress clearly intended to make the alteration of records with the intent to mislead a felony. Pet. App. 6-10. The court emphasized that "in strictly construing a [criminal] statute, courts ought not deprive it of the obvious meaning intended by Congress, nor abandon common sense." *Id.* at 7.

The court of appeals also affirmed the district court's sentencing rulings. It held that the district court correctly applied the Sentencing Guideline applicable to offenses involving fraud or deceit. Pet. App. 10-11. The court further held that the district court correctly assessed the amount of the loss attributable to petitioners' deceit on the basis of petitioners' gain from selling the adulterated drugs. *Id.* at 11-14.

ARGUMENT

1. Petitioners contend (Pet. 17-20) that, under *Neder* v. *United States*, 527 U.S. 1 (1999), the jury was required to find materiality as an element of the offenses under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.* That contention does not warrant review. The court of appeals did not address whether *Neder* requires a materiality finding for convictions under the FDCA. Nor was the resolution of that issue necessary in order to affirm petitioners' FDCA convictions. The jury was instructed to find materiality on the violation on which petitioners sought a materiality instruction, and the failure to give such an

instruction on the other FDCA counts did not constitute plain error.

Petitioners requested a materiality instruction relating to their failure to maintain accurate records. Pet. 19. Although the district court did not give the instruction that petitioners requested, it did instruct the jury that it was required to find materiality. In particular, the court instructed the jury that, in order to find petitioners guilty of failing to maintain accurate records, it was required to find that petitioners "*materially* altered the manufacturing procedures for [Lactulose] by causing sodium hydroxide to be added to this product more than two years after its original manufacture," and in concealing "this unauthorized procedure from the FDA, intentionally failed to document this unproved manufacturing procedure in the production batch records." Tr. 5842-5843 (emphasis added). Assuming that *Neder* requires a materiality instruction, the district court's instruction fulfilled that requirement.

Petitioners did not request a materiality instruction relating to any other FDCA violation. Thus, petitioners' contention that the district court erred in failing to give a materiality instruction on the other FDCA counts is subject to review only for plain error. See Fed. R. Crim. P. 52(b); *Johnson* v. *United States*, 520 U.S. 461 (1997). Under the plain error standard, petitioners must show not only that the court erred in failing to give a materiality instruction. They must also show that (1) the error is "plain" or "obvious," (2) the error "affect[ed] substantial rights" and (3) the error "seriously affect[ed] the fairness, integrity, or public reputation of judicial proceedings." *Johnson*, 520 U.S. at 467-468.

Even assuming that the district court erred in failing to give a materiality instruction on the other FDCA counts, that error was not plain or obvious under *Neder*. In *Neder*, the Court held that the mail fraud, bank fraud, and wire fraud statutes require proof of materiality. The Court reasoned that when Congress criminalizes "fraud," it intends to incorporate fraud's common law materiality requirement unless the statutory context dictates otherwise. 527 U.S. at 23. The FDCA, however, criminalizes violations of the Act that are committed with "the intent to defraud *or mislead*." 21 U.S.C. 333(a)(2) (emphasis added). *Neder* does not address whether such a statute incorporates a materiality requirement. *Neder* therefore does not make it "clear" or "obvious" that the FDCA requires proof of materiality.

Petitioners also cannot establish the other two components of plain error. Count 3 charged petitioners with adulterating the drug Lactulose by adding sodium hydroxide, and Count 6 charged petitioners with distributing the adulterated Lactulose. The jury's finding of guilt with respect to record-keeping, on which a materiality instruction was requested and given, necessarily incorporated a finding that the addition of the sodium hydroxide was a material change. Moreover, petitioners did not contend at trial that adding sodium hydroxide would be insignificant or unimportant; they contended that the conduct did not happen. Tr. 5004, 5254, 5395. Petitioner's own expert witness, Dr. Robyt, made clear that adding sodium hydroxide to Lactulose would be highly material. He testified that sodium hydroxide injected into bottles of Lactulose would be potentially lethal. Tr. 4328, 4334. He further testified that if the sodium hydroxide got into the intestines it could make the patient very sick. Tr. 4338. In those

circumstances, the district court's failure to give a materiality instruction on Counts 3 and 6 neither affected petitioners' substantial rights nor seriously affected the fairness, integrity, or public reputation of judicial proceedings.

Counts 7 and 8 charged that petitioners used contaminated Lactulose concentrate from dented and leaking drums as a drug ingredient and then sold the contaminated drug. The evidence that established that petitioners engaged in that conduct also established its materiality. Specifically, the evidence showed Alra received 36 drums of concentrated Lactulose that were leaking, that under Bhutani's directions, workers injected glue into the leaks and covered the leaks with duct tape, and that Bhutani admitted that the Lactulose concentrate was not fit for human consumption. Gov't C.A. Br. 9. A jury that credited that evidence could not have rationally concluded that petitioners' deception in relation to that conduct was immaterial. Accordingly, the failure to give a materiality instruction on those counts neither affected petitioners' substantial rights nor seriously affected the fairness, integrity, or public reputation of judicial proceedings. Count 10 charged that petitioners distributed K+10 that had been contaminated when a steel pipe was dropped into a blender and ground up into the product during the manufacturing process. Petitioners did not contend that the shipment of drug tablets that were contaminated by metal shards would be insignificant. Rather, they claimed that they destroyed the contaminated portion of the K+10 batch. Govt' C.A. Br. 8-9. The jury, however, rejected petitioners' version of the events, and found that petitioners sold tablets that were contaminated by metal shards. Because a deception relating to selling drugs contaminated with metal shards is obviously

material, the failure to give a materiality instruction on Count 10 neither affected petitioners' substantial rights, nor seriously affected the fairness, integrity, or public reputation of judicial proceedings.

Petitioners were also convicted of conspiring to commit the offenses discussed above. For the same reasons that the failure to give a materiality instruction did not constitute plain error on the substantive counts, it did not constitute plain error on the conspiracy count.

Petitioners contend (Pet. 18-19) that the decision below conflicts with the Ninth Circuit's holding in *United States* v. *Watkins*, 278 F.3d 961 (2002), that the FDCA requires proof of materiality. Because the court of appeals in this case did not address whether the FDCA requires proof of materiality, and because petitioners' FDCA convictions must be affirmed even if the FDCA requires proof of materiality, however, there is no conflict between the decision below and *Watkins*.

2. Petitioners also contend (Pet. 21-23) that review is warranted to decide whether Section 331(e) prohibited the failure to maintain accurate records when their charged conduct occurred. That question does not warrant review. In 1990, Congress clarified that Section 331(e) prohibits the failure to maintain records. See Vaccine and Immunization Amendments of 1990, Pub. L. No. 101-502, § 5(j), 104 Stat. 1289. Petitioners' contention that Section 331(e) did not cover such conduct when their charged conduct occurred therefore does not raise any issue of prospective importance. In addition, under the Sentencing Guidelines, petitioners' convictions for failing to maintain records did not add to the offense level that was produced by their convictions for adulterating the Lacutalose and distributing the adulterated product. A reversal of petitioners' conviction on the failure to maintain records count there-

fore would not have any practical impact on petitioners' sentences.

In any event, the court of appeals correctly held that petitioners' failure to maintain accurate records violated Section 331(e). In 1962, Congress amended the FDCA to require that drug manufacturers provide the FDA with information concerning drugs that the agency had previously approved for sale. That amendment added a new subsection to the FDCA, designated as 21 U.S.C. 355(j) (1994 & Supp. V 1999), which provided in pertinent part:

> (1) In the case of any drug for which an approval of [a new drug application] is in effect, the applicant shall * * * make such reports to the Secretary, of data relating to * * * information * * * with respect to such drug, as the Secretary may by general regulation * * * prescribe.

Drug Amendments of 1962, Pub. L. No. 87-781, § 103, 76 Stat. 782. The same 1962 legislation also amended 21 U.S.C. 331(e) to prohibit any failure to establish or maintain records required by 21 U.S.C. 355(j) (1994 & Supp. V 1999).

The FDCA then remained unchanged for 22 years. In 1984, Congress amended the FDCA to provide for new procedures relating to generic drugs. A new generic drug subsection was designated as Section 355(j), while the previous Section 355(j)—the record-keeping provision—was redesignated as Section 355(k). Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585.

Congress neglected in its 1984 legislation to amend 21 U.S.C. 331(e) to reflect that what had previously been Section 355(j) was now Section 355(k). Section 331(e) therefore continued to prohibit "the failure to

establish or maintain any record * * * required under [21 U.S.C. 355(j)]," even though the new Section 355(j), relating to generic drug approvals, did not include record-keeping and reporting requirements. In 1990, Congress enacted a clarifying amendment to Section 331(e) that struck the reference to Section 355(j) and substituted a reference to Section 355(k). § 5(j), 104 Stat. 1289.

Because petitioners' charged conduct occurred after the 1984 amendments, but before the 1990 clarifying amendment, the relevant question is whether Section 331(e) prohibited the failure to maintain records during that period. In resolving that question, the court of appeals either had to interpret the lingering reference to Section 355(j) as a reference to the redesignated Section 355(k), or it had to give the prohibition in Section 331(e) against failing to establish or maintain required records no meaning at all. The court of appeals correctly chose the interpretation that gave continuing meaning to that prohibition, rather than the one that would have rendered it a nullity. Read in the manner suggested by petitioners, Congress's 1984 amendments to the FDCA repealed the 22-year-old sanction against failure by a drug manufacturer to prepare records that it was still required to maintain, and they did so while still leaving in place language in Section 331 that prohibited the failure to maintain required records. The court of appeals correctly rejected that result as inconsistent with Congress's clear intent and common sense.

This Court and numerous courts of appeals have interpreted criminal laws to prohibit conduct that Congress clearly intended to prohibit notwithstanding the presence of inadvertent drafting errors that rendered the conduct outside the literal reach of the laws. See

United States v. *Lacher*, 134 U.S. 624, 625-632 (1890); *United States* v. *Graham*, 169 F.3d 787, 790-791 (3d Cir.), cert. denied, 528 U.S. 845 (1999); *United States* v. *Warren*, 149 F.3d 825, 827-828 (8th Cir. 1998); *United States* v. *Rossetti Bros., Inc.*, 671 F.2d 718, 720 (2d Cir. 1982); *United States* v. *Scrimgeour*, 636 F.2d 1019, 1021-1024 (5th Cir. Unit B), cert. denied, 454 U.S. 878 (1981); *United States* v. *Moore*, 613 F.2d 1029, 1039-1045 (D.C. Cir. 1979), cert. denied, 446 U.S. 954 (1980); *United States* v. *Babcock*, 530 F.2d 1051, 1053-1054 (D.C. Cir. 1976). The court of appeals' decision in this case is consistent with those decisions.

Petitioners contend (Pet. 21-22) that the decision below conflicts with the decisions in *United States* v. *Faygo Beverages, Inc.*, 733 F.2d 1168 (6th Cir. 1984), and *United States* v. *RSR Corp.*, 664 F.2d 1249, 1253 (5th Cir. Unit A), cert. denied, 459 U.S. 1016 (1982). Neither of those decisions, however, involved an interpretation of Section 331(e). Instead, they involved a construction of two provisions of the Interstate Commerce Act that have since been amended. While there is some tension between the general approach to statutory interpretation adopted by those older decisions and the approach adopted by the court below, that tension is not a sufficient basis for granting review in this case. Should any tension in general approach lead to conflicting interpretations of the same statute, review by this Court might then be warranted. Because there is no conflict in the circuits concerning the correct interpretation of Section 331(e), because the issue arising under Section 331(e) has no prospective importance, and because a reversal of petitioners' conviction on that count would not affect their sentences, review in this case is unwarranted.

3. Petitioners contend (Pet. 22-23) that the district court erred in applying Guidelines § 2F1.1, the fraud Guideline, rather than Guidelines § 2N2.1(b), the drug regulation Guideline. Guidelines § 2N2.1(b), however, expressly states that "[i]f the offense involved fraud, apply § 2F1.1." Since petitioners' conduct involved fraud, the district court correctly applied Guidelines Section 2F1.1.

Nor did the application of Section 2F1.1 violate the Ex-Post Facto Clause. As petitioners note, the Sentencing Commission did not adopt the cross-reference in Section 2N2.1(b) until 1992, after their charged conduct occurred. But the Guidelines in effect at the time of petitioners' criminal conduct also required the application of Guidelines § 2F1.1 to fraudulent conduct. At that time, the commentary to Section 2N2.1 specified that "[i]f the offense involved theft, fraud, bribery, revealing trade secrets, or destruction of property, apply the guideline applicable to the underlying conduct, rather than this guideline." Guidelines § 2N2.1, comment. (n.2) (1988) (emphasis added). That Commentary reflected a binding interpretation of the Guidelines. *Stinson* v. *United States*, 508 U.S. 36, 43 (1993). Thus, even before the Commission adopted the 1992 cross-reference, the courts of appeals uniformly applied Section 2F1.1 to FDCA cases involving the intent to defraud or mislead. *United States* v. *Cambra*, 933 F.2d 752 (9th Cir. 1991); *United States* v. *Anderson*, 45 F.3d 217, 220 (7th Cir. 1995); *United States* v. *Arlen*, 947 F.2d 139, 146 (5th Cir. 1991), cert. denied, 503 U.S. 939 (1992). Because the Guidelines required application of Section 2F1.1 to FDCA cases involving fraud both at the time of petitioners' criminal conduct and at the time of petitioners' sentencing, the district court's use of that

Guideline did not violate the Ex Post Facto Clause. *Johnson* v. *United States*, 529 U.S. 694, 699 (2000).

4. Petitioners contend (Pet. 23-24) that there was insufficient evidence to support the jury's finding that the Lactulose they sold from the leaking drums was contaminated. Specifically, petitioners argue that the jury was required to defer to their expert witness who testified that microrganisms would not have entered the leaking drums. That contention is without merit. On cross-examination, the government established that the witness' opinion was both incomplete and based on limited information. For example, the defense witness admitted that he did not test for mold, dirt, glue residue, or other possible contaminants. Gov't C.A Br. 9. The jury also heard ample evidence that the Lactulose from the leading drums was contaminated. In particular, petitioner Bhutani told an insurance adjuster that the Lactulose concentrate was not fit for human consumption. Gov't C.A. Br. 9. In those circumstances, the court of appeals correctly declined petitioners' "invitation to reweigh the evidence." Pet. App. 15.

5. Petitioners contend (Pet. 25-26) that the district court erred in determining that there was a loss attributable to their fraud under Guidelines § 2F1.1. That contention is without merit and does not warrant review. The district court correctly ruled that, because petitioners' customers did not receive the drugs for which they had bargained, the amount they paid for the drugs should be considered the amount of their loss. The court then adopted a very conservative estimate of that loss—$200,000. Gov't C.A. Br. 44.

The district court's approach is fully consistent with decisions of other courts of appeals construing the fraud Guideline. See *United States* v. *Marcus*, 82 F.3d 606 (4th Cir. 1996); *United States* v. *Gonzalez-Alvarez*, 277

F.3d 73, 78 (1st Cir. 2002). The courts recognize that economic gain, as measured by gross sales, is an appropriate measure of loss when, as here, there is actual, probable, or intended loss to consumers. In the context of adulterated prescription drug sales, economic gain to the manufacturer is the proper measure of loss when drugs do not meet FDA specifications and are thus of unknown value. *Marcus*, 82 F.3d at 608 (a change in formula "rendered the [drug] something other than what it purported to be because the altered formula had not been approved by the FDA and was of unknown safety and efficacy"); *id.* at 610 ("as such, consumers did not receive that for which they bargained—an FDA-approved drug of *known* safety and efficiency").

Petitioners err in asserting (Pet. 25) that the Seventh Circuit's ruling on that point conflicts with the Fourth Circuit's ruling in *United States* v. *Chatterji*, 46 F.3d 1336 (4th Cir. 1995). In *Chatterji*, the Fourth Circuit held that customer loss should not be used where the efficiency and safety of the drug is not implicated by the defendant's conduct. In *Marcus*, the Fourth Circuit subsequently clarified that *Chatterji* does not apply where, as here, the adulteration of the drug implicates the safety and efficiency of the product. The court of appeals here expressly followed the rationale of *Marcus*. Pet. App. 12-14. Thus, there is no conflict on that issue between the Seventh and Fourth Circuits. In any event, any conflict in interpretation of the Guidelines is appropriately resolved by the Sentencing Commission. *Braxton* v. *United States*, 500 U.S. 344, 347-348 (1991).

6. Finally, petitioners contend (Pet. 26-30) that they should have obtained a new trial because the government presented a different theory on appeal than the one it presented to the jury. In petitioners' view, the

government's theory at trial was that the Lactulose was medically ineffective or would soon become medically ineffective, and that petitioners' spiked the Lactulose to mask that fact, while the government's theory on appeal was that petitioners' spiked the Lactulose in order to mask its age. After "[a] second read of the trial transcript," however, the court of appeals determined that "the government's position at trial and on appeal has been consistent." Pet. App. 2. In particular, the court found that "[t]he government did not show at trial that the [old] Lactulose was outside the accepted pH range or medically ineffective; rather it admitted that the pH was at all times within range, but that it was dropping, which signaled degradation." *Id.* at 2-3. The court further determined that the government's theory at both stages was that, "in order to mask any degradation the defendants raised the pH by adding sodium hydroxide so that the fact that it was being sold past its expiration date could not be detected." *Id.* at 3. None of the excerpts from the trial cited by petitioners (Pet. 27-30) undermines the court of appeals' determination. In any event, that fact-bound issue does not warrant review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

THEODORE B. OLSON
Solicitor General

ROBERT D. MCCALLUM, JR.
Assistant Attorney General

DOUGLAS N. LETTER
ROBERT M. LOEB
LAWRENCE G. MCDADE
Attorneys

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ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

REPLY BRIEF OF PETITIONERS

MARK LONDON
Counsel of Record
CHRISTOPHER B. MEAD
LONDON & MEAD
1225 19th Street, N.W.
Suite 320
Washington, D.C. 20036
(202) 331-3334

MARK L. SHAW
33 North County Street
Suite 302
Waukegan, Illinois 60085
(847) 244-4696

Counsel for Petitioners

THE LEX GROUP[DC] ◆ One Massachusetts Ave., NW ◆ Suite 670 ◆ Washington, DC 20001
(202) 789-2400 ◆ (800) 815-3791 ◆ Fax: (202) 789-1911 ◆ www.thelexgroupdc.com

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REPLY BRIEF FOR PETITIONERS

I. THE GOVERNMENT DOES NOT DISPUTE THE MERITS OF THE NINTH CIRCUIT'S HOLDING IN *UNITED STATES V. WATKINS*.

Defendant Raj Bhutani has been sentenced to 30 months in prison for committing violations of the FD&C Act with "intent to defraud or mislead." The jury was not instructed that it had to find the violations were material. Three years after the jury's verdicts, this Court held that when Congress used the common law term "to defraud" in the mail and wire fraud statutes, it necessarily incorporated materiality as an element of the offense. *United States v. Neder*, 527 U.S. 1 (1999).

On January 29, 2002, the Ninth Circuit held that this Court's *Neder* opinion required a finding that materiality was an element of an "intent to defraud or mislead" under the felony provisions of the FD&C Act. *United States v. Watkins*, 278 F.3d 961 (9th Cir. 2002). The United States did not seek review of the *Watkins* panel opinion, and the Brief for the United States in Opposition in this case ("Opposition") does not argue that *Watkins* is wrong, or that *Neder*'s reasoning does not apply to the FD&C Act's felony provisions. Instead, the government argues that Defendants' request for a materiality instruction was incomplete, that the evidence proved that the offenses were material, and that the Seventh Circuit's failure to specifically address the fully-briefed materiality issue means that there is no published conflict between the Seventh Circuit's opinion here and the Ninth Circuit's opinion in *Watkins*. Opposition at 5-10.

This Court does not have to reach government arguments that the Seventh Circuit did not address. If the government does not dispute that materiality is an element of the FD&C Act's felony provisions, this Court should remand to the Seventh Circuit for reconsideration in light of *Watkins*, or

resolve the conflict between *Watkins* and the Seventh Circuit's ruling in this case.

Defendants did request a materiality instruction. Counsel told the district judge, "I want to preserve our objection to your failure to grant Alra request No. 12, which is the request for a materiality requirement on the failure to maintain records charges on that prong of the conspiracy count." Tr. 5863. The district judge responded, "In regard to the point about the failure to maintain records, my view on that, as I stated earlier this morning off the record, is that the regulations required the maintenance of these records and that establishes the need to keep them and to ask the jury to go beyond that and determine whether the records required to be kept by a federal regulation were material or not would be to give the jury the authority to modify the regulations, which I don't think would be a good idea." Tr. 5868.

The Indictment alleged that Defendants conspired to commit the object offense of a failure to maintain required records. Count One, paragraph 10(b)(J.A. 73). Accordingly, a request to define that object offense in the conspiracy count applied to all counts alleging a violation of Current Good Manufacturing Practice ("CGMP"), which includes a requirement of maintaining accurate records. *See* Count One, paragraph 9; Count Three; Count Six; Count Ten (J.A. 71, 87, 91, 99). The district judge refused a defense request to define how Defendants were alleged to violate CGMP on Count Ten, meaning that the jury may have convicted on Count Ten based on a record-keeping theory. Tr. 5867. The district judge's rationale for denying the requested materiality instruction applied to all counts alleging a failure to maintain records. The failure to give a materiality instruction on all FD&C counts was also plain error. *See Johnson v. United States*, 520 U.S. 461, 468 (1997)(error measured by established law at time of appeal).

The government argues that on Count Four alone, the jury was instructed that it had to find the Defendants "materially altered the manufacturing procedures." Opposition at 6. First, the district judge did not give a similar instruction on Counts One, Three, Six, and Ten. Second, there is a distinction between materially altering a "manufacturing procedure," and maintaining batch records. The district judge refused to tell the jury that any inaccuracies in the records had to be material, clearly believing that was not the law, and reflecting his belief that the instructions as a whole did not tell the jury that such a requirement existed. And third, Count Four did not charge a crime. *See* section II. below.

The government's description of the facts in support of its plain error analysis is inaccurate and incomplete. The district judge who presided over the trial wrote, "It seemed to the court at the time that the verdict could have gone either way . . . ." App. 64. On Counts Three, Four, and Six, where the government alleged that adding sodium hydroxide was a violation of the FD&C Act, Defendants did contend that the conduct did not happen, but also noted that the FDA had approved adding sodium hydroxide to the product. Defendants testified that adding sodium hydroxide was just repeating a step in the FDA-approved manufacturing process, and that FDA did not consider repeating a step in an approved manufacturing process to be a violation of CGMP. Tr. 5153-56, 5402, 5408-09. There was no evidence that the Bhutanis directed employees to falsify batch records; to the contrary, a mid-level supervisor who did not speak good English told employees what to write on the batch records to describe the reprocessing operation. Tr. 1740-41, 4407-11.

The government argues that testimony from defense expert Dr. Robyt that improperly mixed sodium hydroxide would have burned the mouths of patients demonstrated that the addition of sodium hydroxide was material.

Opposition at 8. The government has this argument backwards. There were no complaints of any burning sensations from customers, demonstrating that it was highly improbable that more sodium hydroxide was added at all, and conclusively proving that if sodium hydroxide was added, it was mixed sufficiently. With the government changing its position on appeal and conceding that the product was medically effective and stable, and in the absence of consumer complaints, the government's evidence failed to prove an intent to defraud with respect to a material matter. As the district court said at sentencing:

> Taking the counts one by one, there is no evidence that Dr. Bhutani regarded the injection of Lactulose into the individual bottles with syringes as creating a risk of serious bodily harm to people who might use the Lactulose Syrup. What was being injected was sodium hydroxide, which was something that was normally added to the drug. What occurred here was that it was added in a different manner than authorized by regulations, and the addition in that manner was not documented. . . .
>
> The government had itself changed its position as to what the risk was at least three times during the course of this litigation. It told the jury at trial that the risk was in the Lactulose itself in that it had degraded or decomposed to the point where it was no longer medically effective and that the injections of the sodium hydroxide were made to mask or conceal that fact. . . .
>
> When the case went up on appeal, the government took a different position . . . .

Tr. 1/24/00 at 39-41.

For the reasons stated in Section IV below, unrebutted defense expert testimony demonstrated that the use of lactulose raw material that arrived in leaking drums (Counts Seven and Eight) did not create a reasonable possibility of contamination. Perhaps most damning to the government's case on materiality, FDA inspector Stojak arrived at Alra's plant within weeks after the leaking drums were used, and heard directly from Dr. Bhutani that Alra had used material from leaking drums. Stojak did not even write up the use of the drums as a violation of the FD&C Act on his inspection report, and took no steps to recall the batch or initiate any enforcement action. Tr. 4028-4052.

As the district court said at sentencing: "there is no evidence whatever that the Lactulose that was used from the leaking drums had anything medically dangerous about it or that it would cause anybody any injury." Tr. 1/24/00 at 39-41.

The Opposition summarizes the evidence on Count Ten by saying, a Asteel pipe was dropped into a blender and ground up into the product, "and that such an event would be "obviously material." Opposition at 9 (emphasis added). First, such an event would be "obviously" impossible; a steel pipe hitting a moving grinder blade would stop the machinery. There was no evidence that a steel pipe was "ground up." Romiro Gonzalez, an ex-Alra employee with no motive to lie, testified that his brother Bernabe had let the pipe slip into a Fitzmill, and showed him the mangled pipe afterward. Romiro took the pipe to Dr. Bhutani, who told him to throw away the barrel of product that had been under the grinder at the time of the accident. Tr. 5179-81. Tr. 5179-81. Eleanor Campbell and Dr. Bhutani said the same thing. Tr. 2699, 5281-82. Carol Hacker, one of the government's key witnesses, had recorded the destruction of a drum of K+10. Tr. 1342-43 (J.A. 538). Hacker testified that Dr. Bhutani told her to use magnets to search for metal, and that she removed all the metal she could see. Tr. 1346.

Joyce Meton, a key government witness, testified that the magnets were picking up the metal. Tr. 1779. FDA District Director Raymond Mlecko testified that, at a meeting with Dr. Bhutani in 1991, FDA representatives did not disagree that the use of magnets to search for metal contamination was common in the industry. Tr. 3914. FDA did exhaustive lab testing on Alra's products looking for metal, and found none. Tr. 3211.

The failure to give a materiality instruction seriously affected petitioners' substantial rights and the fairness, integrity, and public reputation of judicial proceedings in this case.

II. THERE IS NO AMBIGUITY IN THE PLAIN LANGUAGE OF SECTION 331(e); COUNT FOUR AND AN OBJECT OF THE CONSPIRACY DID NOT ALLEGE A CRIME.

At the time of the conduct alleged in Count Four of the Indictment, the charged statute, 21 U.S.C. 331(e), provided that "the failure to establish or maintain any record . . . required under [21 U.S.C. 355(j)]" was a violation of the FD&C Act. 21 U.S.C. 355(j) did not include record-keeping requirements. The government's Opposition says that the Seventh Circuit's opinion upholding the convictions on Count Four "gave continuing meaning" to 331(e)'s reference to "establish[ing] or maintain[ing]" records. Opposition at 12. But the Seventh Circuit's opinion did not suggest there was any ambiguity in the statutory language. As the Seventh Circuit recognized, "the plain language of the statute did not penalize [Defendants'] conduct." App. 6.

The government does not dispute that this issue is a fundamental question of democratic theory, or that requiring Congress to specify criminal conduct is a restraint on the power of the prosecution to create crimes through interpretations of legislative intent. Further, the government's Opposition fails to address the crucial point

that section 331(e) was one of the object offenses alleged in the conspiracy charged in Count One. (J.A. 73).

III. THIS COURT SHOULD CORRECT THE SEVENTH CIRCUIT'S ERRONEOUS HOLDING THAT "JUDGES MUST APPLY THE GUIDELINES IN FORCE WHEN A DEFENDANT IS SENTENCED," AND REMAND.

The government's Opposition does not dispute that the Seventh Circuit's rejection of an ex post facto argument with the holding that "judges must apply the guidelines in force when a defendant is sentenced" is an incorrect statement of law that conflicts with all other federal circuits that have considered the issue. App. 11; Opposition at 14. Instead, the government argues "no harm, no foul," because the commentary to U.S.S.G. 2N2.1 at the time of the charged conduct provided that "[i]f the offense involved . . . fraud, . . . apply the guideline applicable to the underlying conduct." Defendants have substantial arguments that the underlying conduct here does not involve a 2F1.1 fraud. Guideline 2N2.1 has always applied to knowing conduct that violates the Food, Drug & Cosmetic Act. Application Note 1 provides, "This guideline assumes a regulatory offense that involved knowing or reckless conduct." Cases like this one, alleging an intent to defraud FDA, where the jury is instructed that "[i]t is not necessary . . . that the defendant intended to cause economic loss," J.A. 497, fit that category. At most, the government's evidence showed knowing, technical violations of the FD&C Act. This Court should correct the Seventh Circuit's error of law and remand for reconsideration of Defendants' sentencing arguments.

IV. THE GOVERNMENT DOES NOT ADDRESS THE LEGAL EFFECT OF UNREBUTTED EXPERT TESTIMONY DENYING AN OFFENSE ELEMENT.

The government's Opposition does not address the legal basis for certiorari, that the Seventh Circuit's opinion

conflicts with precedent from other circuits finding that unrebutted defense expert testimony denying an element of the offense rendered the government's evidence insufficient as a matter of law. Instead, the government argues that Dr. Robyt's testimony was based on incomplete information. That is not true. For a complete summary of the essentially undisputed facts on Counts Seven and Eight, *see* Petitioners' brief to the Seventh Circuit at 28-36, 43-48.

The government repeatedly refers to an allegation that Dr. Bhutani instructed employees to inject glue into the leaks in the drums. That allegation came solely from the uncorroborated testimony of James Ward, who was fired for incompetence and committed repeated, demonstrable perjury. No one saw any glue on the drums, photographs of the drums did not show any glue, and FDA inspector Stojak testified that during September 1989, he saw drums with tape, but did not see any glue, even though he was looking for it. Tr. 2206-20, 2277, 4023-24. For a catalogue of Ward's demonstrated, extensive lies, *see* Petitioners' brief to the Seventh Circuit at 28-36, 43-48. Dr. Bhutani's preliminary opinion that the drums could not be used came before Alra's Quality Control lab tested each drum and found no contamination.

V. THE GOVERNMENT IGNORES THE SEVENTH CIRCUIT'S HOLDING THAT VIOLATIONS OF A REGULATORY SCHEME, NOT "THE MEDICAL [IN]EFFECTIVENESS OF THE DRUG," ARE SUFFICIENT TO PROVE A "FRAUD LOSS."

The government's Opposition argues that the Seventh Circuit's opinion is consistent with *United States v. Marcus*, 82 F.3d 606 (4th Cir. 1996), because this case "implicates the safety and efficacy of the [Defendants'] product[s]." Opposition at 16-17. That is not what the district court or the Seventh Circuit said. The district court found that there was "no evidence of any actual contamination" (1/24/00

hearing at 40-41), that this "was a paper case" about "failure to keep records," that there was "no showing of any harm to anybody" (2/15/00 hearing at 124), and that there was "no evidence that anyone was likely to be hurt from these tiny metal fragments that were in some of the pills" (1/24/00 hearing at 41). In conflict with *Marcus* and many other cases, the Seventh Circuit panel rejected the idea that safety and efficacy of the products controlled. The panel wrote: "[t]he medical effectiveness of the drug or its dangerousness after adulteration ought not to be the core of the inquiry; . . . there was indeed loss to consumers because consumers bought drugs under the false belief that they were in full compliance with the law." App. 13.

If the Sentencing Commission ever resolves the conflict between the Seventh Circuit's opinion here and *United States v. Maurello*, 76 F.3d 1304, 1312 (3d Cir. 1996); *United States v. Chatterji*, 46 F.3d 1336 (4th Cir. 1995); *United States v. Haas*,171 F.3d 259, 269-70 (5th Cir. 1999); *United States v. Barnes*, 125 F.3d 1287 (9th Cir. 1997); *United States v. Haddock*, 12 F.3d 950, 960-61 (10th Cir.1993); and *United States v. Prigmore*, 1996 U.S.Dist. Lexis 11695 (D.Mass. 1996), it will be cold comfort to Dr. Bhutani while he serves 30 months in prison.

VI. THE GOVERNMENT REFUSES TO CORRECT ITS MISREPRESENTATIONS TO THE SEVENTH CIRCUIT.

The government asked the jury to convict Defendants on Counts Three and Six on the grounds that the Lactulose from lots 52-230 and 52-231 "had decomposed so that it no longer met applicable testing specifications." (Jury instructions, J.A. 501). Government counsel told the district court three days before trial that "the government's theory of the case" was that the Lactulose Syrup was "no longer stable" before the sodium hydroxide was added. Tr. 12/4/95 at 5. Government counsel told the district judge during Rule 29 argument that the evidence presented to the

jury proved that Alra's Lactulose was medically ineffective before the alleged addition of sodium hydroxide. Tr. 4232-3. Government counsel told the jury during closing argument that "Lactulose is an unstable sugar." Tr. 5612 (emphasis added).

In its brief to the Seventh Circuit, the government said it told the jury exactly the opposite of what it told the district judge, and exactly the opposite of its theory of conviction on Counts Three and Six: "the government represented to the jury that the Lactulose in question was at all times within approved specifications." Govt. Br. at 15. The district court knows that the government changed its position on appeal. App. 19. Petitioners' counsel has repeatedly asked the Department of Justice to correct its misrepresentations to appellate courts in this litigation. *See* letters from Petitioners' counsel to Department of Justice, attached to this reply.

The Opposition's refusal to correct the record is one more act in an ongoing judicial scandal.

CONCLUSION

The petition for a writ of certiorari should be granted.

Mark London
(Counsel of Record)
Christopher B. Mead
London & Mead
1225 19th Street, N.W., Suite 320
Washington, D.C. 20036
(202) 331-3334
Counsel for Alra Laboratories, Inc.

Mark L. Shaw
33 North County Street
Suite 302
Waukegan, IL 60085
(847) 244-4696
Counsel for
Baldev Raj Bhutani

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London & Mead
1225 19th St., N.W., 7th Floor
Washington, D.C. 20036

January 10, 1999

Lawrence G. McDade
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044

Deborah S. Smolover
Counsel to the Deputy Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, D.C. 20530

Douglas N. Letter
Robert M. Loeb
Attorneys, Appellate Staff
U.S. Department of Justice
Room 9136 PHB
601 D St., N.W.
Washington, D.C. 20530-0001

Re: United States v. Bhutani, et al.

Dear Counsel:

Defendants feel that they are witnesses to a judicial scandal, but no one is listening. The government told the Seventh Circuit things that were not true, and the Seventh Circuit relied on those factual errors in its opinion. Defendants have filed a petition for certiorari, but the Supreme Court takes only 100 cases a year. Unless someone inside the Department of Justice takes the time to understand the details of this case, and to understand why the government's representations to the Seventh Circuit were wrong, a grave injustice will occur.

FACTUAL BACKGROUND

After a ten-week trial, the jury convicted Dr. Baldev Raj Bhutani, his wife Neelam Bhutani, and Alra Laboratories, Incorporated ("Alra") of conspiracy and various violations of the Federal Food, Drug and Cosmetic Act ("FD&C Act"). The Bhutanis own and run Alra, a generic drug manufacturer.

The lead allegations in the Indictment, which were the primary focus at trial, related to Alra's manufacture of lots 52-230-P and 52-231-P of Lactulose Syrup, USP. Lactulose Syrup is a prescription laxative, produced in liquid form, that treats liver disease by removing ammonia that builds up in the colon. Tr. 1575, 1691-97.

Alra first mixed the bulk solutions for lots 52-230 and 52-231 in June, 1986, and bottled the lots. After getting approval to market Lactulose Syrup from the Food and Drug Administration (AFDAA) in July, 1988, Alra's Quality Control laboratory tested samples from both lots. Each lot assayed at 100% of label claim for the active ingredient, and the pH values for the two lots ranged from 5.3 - 5.6, well within the approved pH range for Lactulose Syrup of 3.0 - 7.0. Lab tests for related substances, which are measurements of saccharides that would be present if the active ingredient was breaking down, were also well within limits. Joint Appendix in the Seventh Circuit ("J.A.") at 377, 398.

The Government contended that despite these passing lab results, Defendants nonetheless believed that the lots were "degraded" and "decomposed," and that to mask that decomposition, seven Alra employees unpacked both lots from storage crates, opened each of approximately 3,300 bottles from the two lots, added sodium hydroxide (an ingredient in Alra's FDA-approved formulation) bottle-by-bottle with some

sort of turkey baster or syringe, shook the bottles, recapped the bottles, labeled them, and repacked them in crates. The Government alleged that this process violated the FD&C Act because Alra's approved manufacturing process required that sodium hydroxide be added in a mixing vat during the initial manufacture of Lactulose Syrup. The Government also charged that Alra created false batch records because the employees failed to document the alleged addition of sodium hydroxide. J.A. 65-66, 69-70. The defense acknowledged that seven employees had unpacked the bottles, replaced some leaking caps, labeled the bottles, and repacked them, but the defense denied that additional sodium hydroxide had been added as alleged in the Indictment.

Defendants were convicted of conspiracy and various substantive counts.

In May, 1996, three months after the jury's verdict, the United States Pharmacopeia ("USP") proposed a downward revision of the acceptable pH range for Lactulose, from 3.0 - 7.0 to 2.5 - 6.5. The USP based its proposal on data submitted by UDL, another manufacturer of Lactulose. The USP proposal stated:

> [b]ased on information received that stability data has shown a downward trend in pH over time, it is proposed to revise the pH range in this monograph. The proposed pH change is reported not to have any significant impact on the safety and quality of this product: it does not in any way affect the laxative properties of the product, and it does not affect the level of the related substances.

J.A. 284-85.

The defense filed a Motion for a New Trial Based on Newly Discovered Evidence And/Or Violation of Brady v. Maryland, arguing that the data cited by the USP was in the possession of FDA before the trial and undercut the Government's theory that a decline in pH correlated to a decline in medical effectiveness. J.A. 269-85. The defense followed up with a motion for discovery, requesting the stability data from other manufacturers of Lactulose in FDA's files. J.A. 292. The district court ordered discovery over the Government's opposition. J.A. 301.

The data from other manufacturers that was in FDA's files before trial showed that there was no correlation between a decline in pH and the potency of the product; showed that Lactulose was stable as a rock, plateauing at over 90% of label claim for years after manufacture even as pH declined to 3.0 and below; and showed that there was no "cascading" effect or accelerated degradation of the product at pH values of 3 or below. See Memorandum in Support of Post-Trial Motion, filed May 12, 1997; J.A. 343-51. Discovery revealed that on August 15, 1994, UDL had submitted its stability data to FDA showing no correlation between a decline in pH and the potency of the product, and had asked FDA to revise the pH range downward. A year later the Government argued a scientific theory to the jury directly contrary to the UDL data.

Data in FDA's files before the trial exposed the Government's theory of motive as fiction. Government counsel had argued that Alra wanted to increase the pH of the Lactulose lots to "make sure that if anyone tested the pH of the drug product, it would test high. They wouldn't know it was old, they wouldn't know it had degraded." Tr. 5585. Alra was the first generic manufacturer of Lactulose approved by the FDA. And lots 52-230 and 52-231 were among the first five lots that Alra released. The other three lots that Alra released at roughly the same time had pH values ranging between 4.9 and 5.85 at

the time of release. Alra's customers thus would not have known anything about the age of lots 52-230 and 52-231 from comparing their pH values to other Alra lots.

Post-trial Brady discovery revealed that Merrill Dow, the name brand manufacturer that had monopolized the market for Lactulose in the U.S. for years, generally released product with initial pH values between 4.0 and 5.0. According to the Government's theory that a higher pH value would indicate a "newer" product, any sophisticated customers familiar with Lactulose would have believed that any product with a pH above 4.5 was "new." There was thus no motive at all for Alra to increase the pH of its lots.

The Government did not call any Alra customers at trial to testify that they would have believed that a product with a pH of 4.6 was "old." In light of the revelation that the innovator routinely released product with pH values between 4.0 - 5.0, defense counsel doubt that the government even asked any Alra customers whether they would have recognized the "age" of any batches based on pH values well within specifications. It appears that the Government constructed this theory based on speculation, without ever checking the contrary evidence in FDA's files.

The district court requested extensive briefing from the parties summarizing the stability data that had been in FDA's possession before trial, and on the government's use of the word "degradation" during trial. Finally, in a 30-page Memorandum Opinion that quoted extensively from the government's arguments to the jury and its questions to expert witnesses, the district court found that the government had suppressed the stability data in FDA's files, that the data was favorable to the defense, and that the data was material. Explicitly finding that the stability data in FDA's files "seriously undermines the court's confidence in the verdicts,"

the district court granted Defendants' motion for a new trial. Memorandum Opinion, 12/17/97, Appendix B to Petition for Cert.

The government appealed. On appeal, the National Pharmaceutical Alliance "(NPA"), a national trade association representing more than 160 generic pharmaceutical manufacturers, distributors, and related firms, was granted leave to file a brief amicus curiae. The NPA was concerned about the government's argument that the prosecution team had no obligation to search FDA's files for exculpatory materials in an FD&C Act prosecution. The NPA argued that because of the FDA's "special place in our health care system:"

> [i]t is absolutely necessary that the FDA be obligated to take enforcement action only when-as an agency-it can assure the Court that its position is fully supported by the data and information in its files. To suggest that it may proceed in a civil or criminal matter without conducting a thorough review of its own files is absolutely contrary to the responsibility that Congress has placed on the agency.

Brief Amicus Curiae of the National Pharmaceutical Alliance in Support of Affirmance, at 2.

I. THE SEVENTH CIRCUIT'S OPINION ADOPTED THE GOVERNMENT'S MISRERESENTATIONS ABOUT THE PROSECUTION'S ARGUMENTS AT TRIAL.

In briefing, the government told the Seventh Circuit that it "did not dispute that before being spiked with sodium hydroxide [lots 52-230 and 52-231] were within the pH range, medically effective, and stable." Reply Brief of Appellant at 6.

Government counsel repeated that position during oral argument, saying:

> we never argued the material was decomposed due to its aging. The only decomposition which comes into matter from the evidence produced at trial was once they added the sodium hydroxide to it that then sent a chain of events into causation here including the acceleration of the degradation of the drug so it's possible that after they added the sodium hydroxide then it at least in part was a decomposed product.

During oral argument on appeal, the government said that it had argued that the Lactulose was dangerous only after the alleged addition of sodium hydroxide:

> That's true we so argued [that the product was dangerous] but what Judge Grady said is that we argued that they spiked it because it was dangerous before they spiked it. There's a big difference from saying it was dangerous after they spiked it which the defense expert Robyt testified as well, that if by spiking the bottle by bottle with sodium hydroxide that would be greatly dangerous there was no dispute on that as well. So that evidence in testimony about after spiking it being dangerous simply does not support the district court, the district court's holding here.[1]

---

[1] Transcription from tape of oral argument.

The Seventh Circuit adopted the government's argument, writing, After reviewing the trial transcript, we do not agree that the government's argument was premised on the fact that ALRA spiked the Lactulose lots because they would soon be unfit for use. In fact, the government did not argue that the Lactulose was unfit, or close to unfit." 175 F.3d at 578.

II. THE GOVERNMENT CONTENDED THAT THE LACTULOSE WAS MEDICALLY INEFFECTIVE, UNSTABLE, AND "CLOSE TO UNFIT" THROUGH INDICTMENT, TRIAL, AND SENTENCING SUBMISSIONS.

A. That The Lactulose Was "Decomposed" And Unfit Before The Alleged Addition Of Sodium Hydroxide.

On January 12, 1994, FDA Inspector Joseph Stojak summarized to the grand jury the evidence supporting the government's proposed superseding indictment. He testified:

> They went back-when they tested the product, they found that the pH, an indicator of the stability of the product, had dropped significantly. They went back in, opened up each of the caps and actually syringed in additional sodium hydroxide into the container, closed the caps, and shook them up.
>
> What they were trying to do and what they ultimately convinced themselves they did was that they raised the pH, and therefore, the product was good again.

Q. When you say that the increase of pH and the injection of sodium hydroxide would mask the degradation of the product-is that right?

A. -Exactly, the pH-

Q. -It was not actually restored, in fact, to its previous position?[2]

A. No, it wasn't restored at all, but it would mask this by, if anyone were to check the product, they would say the pH is within range; therefore the product must be good.

. . .

Q. What happened after the injection of sodium hydroxide into the finished lots-were the bottles then relabeled?

A. Yes, they were relabeled, and this is a very odd situation. They relabeled them-keep in mind they were made in '86 and they're allowed to have an eighteen-month expiration, and here we're all the way into '88-they relabeled these products with a September of 1989 expiration date.

Q. So the product had in fact already expired; is that right?

A. It had long expired.[2]

---

[2] Grand jury testimony of Joseph Stojak, 1/12/94, at pp. 20-21 (emphases added).

Agent Stojak clearly told the grand jury that Lactulose lots 52-230 and 52-231 were no good before the alleged addition of sodium hydroxide. He testified that the lots had "expired." According to the government's position before the Seventh Circuit, Inspector Stojak really said:

> They went back-when they tested the product, they found that the pH, [which is not an indicator of the medical effectiveness of the product], had dropped [in a way that did not affect the stability or medical effectiveness of the product]. They went back in, opened up each of the caps and actually syringed in additional sodium hydroxide into the container, closed the caps, and shook them up.
>
> What they were trying to do and what they ultimately convinced themselves they did was that they raised the pH, and therefore, the product [that had been safe, medically effective, and stable, was now dangerous].
>
> Q. When you say that the increase of pH and the injection of sodium hydroxide would mask the degradation of the product [that was safe, medically effective and stable]-is that right?
>
> A. -Exactly, the pH-
>
> Q. -It was not actually restored, in fact, to its previous position [of being medically effective and stable]?[3]

---

[3] Grand jury testimony of Joseph Stojak, 1/12/94, at pp. 20-21 (emphases added).

A. No, it wasn't restored at all [the Defendants had changed the product from being safe, medically effective and stable to being dangerous, and the new pH level which had caused this dangerous condition], would mask this by, if anyone were to check the product, they would say the pH is within range; therefore the product must be good.

. . .

Q. What happened after the injection of sodium hydroxide into the finished lots-were the bottles then relabeled?

A. Yes, they were relabeled, and this is a very odd situation. They relabeled them-keep in mind they were made in '86 and they're allowed to have an eighteen-month expiration, and here we're all the way into '88-they relabeled these products with a September of 1989 expiration date.

Q. So the product had in fact already expired [but was still safe, medically effective, and stable]; is that right?

A. It had long [been safe, medically effective, and stable, and would have been stable and medically effective for years if Defendants hadn't added the sodium hydroxide].

B. The Indictment Alleged That The Lactulose Was "Decomposed" Before The Alleged Addition of Sodium Hydroxide.

Overt Act 2 in the conspiracy count alleged: "BALDEV RAJ BHUTANI and NEELAM BHUTANI directed ALRA employees to add an undocumented substance, namely additional amounts of Sodium Hydroxide (NaOH), to partially decomposed Lactulose in the finished generic drug product Lactulose Syrup, USP. . . ." (Emphasis added).

Overt Act 5 in the conspiracy count alleged: "BALDEV RAJ BHUTANI and NEELAM BHUTANI caused the shipment from Gurnee, Illinois to Brooklyn, New York, of an adulterated ALRA generic drug product, Lactulose Syrup, USP, lot number 52-230-P, which contained a decomposed substance, namely decomposed Lactulose, and an undocumented and unapproved substance, namely additional amounts of Sodium Hydroxide (NaOH)." Counts 3 and 6 of the Superseding Indictment also alleged that lots 52-230 and 52-231 "consisted in part of a decomposed substance, namely decomposed lactulose raw material."

Overt Act 2 did not allege that the Lactulose became decomposed after the addition of sodium hydroxide. Instead, it alleged that Defendants added sodium hydroxide to "partially decomposed Lactulose."

The Indictment provides conclusive proof that the Government alleged that the Lactulose was not medically effective, stable, fit, or close to fit. According to the government's current theory of its allegations, the Indictment should have read: "BALDEV RAJ BHUTANI and NEELAM BHUTANI directed ALRA employees to add an undocumented substance, namely additional amounts of Sodium Hydroxide

(NaOH), to [medically effective, stable, and fit] Lactulose in the finished generic drug product Lactulose Syrup, USP . . . ."

C. The Government's Expert Witness Disclosure Emphasized That pH Was Evidence of "Degradation."

Before trial, the government filed an expert witness disclosure. That disclosure said that Kevin Hicks, Ph.D., would testify that "degradation of Lactulose can be evidenced by a reduction in the solution's pH. Raising of the pH through the addition of NaOH may mask the detection of the degradation of Lactulose, but it would not reverse the degradation process." Expert Witness Disclosure at p. 2. The Expert Witness Disclosure said that the addition of sodium hydroxide would "mask" degradation that had already occurred.

Acording to the government's theory in front of the Seventh Circuit, the Expert Disclosure really meant: "[insignificant] degradation of Lactulose can be evidenced by a reduction in the solution's pH [that would not indicate that the product was unsafe, unstable, or medically ineffective]. Raising of the pH through the addition of NaOH may mask the detection of the [insignificant] degradation of Lactulose, but [would cause the product to be unsafe and medically ineffective and unstable]."

D. At A Hearing One Month Before Trial, The Government Stated That It Would Call An Expert To Testify That The Product Had Decomposed Due To Its Age.

At a hearing on November 8, 1995, one month before trial, the Court asked government counsel what kind of expert testimony it would present. Government counsel said:

> Your Honor, we will have a chemist who will describe what Lactulose, Lactulose being one of the drugs in question, is, basically what happens to it after time, the charge being that it was sold after its expiration date; so from the standpoint of an expert in carbohydrates and sugar chemistry will describe what in fact it was several years after manufacture.
>
> . . .
>
> . . . That will be followed by a gastroenterologist who will be from the FDA Center for Drug Evaluation Research, specifically a fellow by the name of Dr. John Senior who will testify as to why with those changes it would not have the same therapeutic effect from the standpoint of a gastroenterologist.

Tr. 11/8/95 at 11 (emphasis added). Government counsel was not discussing "changes" from the alleged injection of sodium hydroxide; counsel was discussing "changes" as a result of the aging of the product. The government told the Seventh Circuit, "we never argued the material was decomposed due to its aging."

E. Three Days Before Trial, The Government Argued To The District Court That Lactulose Lots 52-230 and 52-231 Were "No Longer Stable."

On December 5, 1995, three days before trial, government counsel told this Court at a hearing that "it is the government's theory of the case-after but prior to the manufacture, three years and stuck in storage, it then was approved. It was approved in an 18-month [expiration] date

based on stability data that was submitted. Then after 18 months, it was no longer stable. It no longer could be assured that it is what it originally was." Tr. of 12/5/95 hearing at 5.

F. In Opening Statement The Government Argued That The Lactulose Was Not Stable.

Contrary to its representations to the Seventh Circuit that it "did not dispute that [lots 52-230 and 52-231] were . . . medically effective and stable" before the alleged addition of sodium hydroxide, government counsel argued in opening statement that the lots had "expired," and that attempting to market them was doing the "wrong thing:"

> But then the Bhutanis chose to do the wrong thing. Alra received its ANDA approval to sell Lactulose in August of 1988. Now, that was a full two years after the initial 1986 batches were manufactured. The government will show you that on the week that Alra's ANDA for Lactulose was approved, the defendants Baldev Raj Bhutani and Neelam Bhutani instructed their employees to label the bottles of Lactulose that had been manufactured in 1986 with a September 1989 expiration date.
>
> Now, that date was over three years from the date the product was actually manufactured, well beyond the 18-month approved and accepted expiration date. And then they took that mislabeled expired product and they shipped it out the door.

Tr. 12/8/95 at 15-16 (emphases added). The government told the jury that the product was "expired" because of its age. The

government told the Seventh Circuit that "we never argued the material was decomposed due to its aging."

G. The Government Stated Its Theory That A Decline In pH Showed "Degradation" In Its Opening Statement.

In her opening statement, Government counsel argued:

> The defendants instructed their employees to open up the bottles of Lactulose, those 1986 bottles, and inject a chemical called sodium hydroxide into the bottles in order to raise the pH and make it appear that the product had not, in fact, degraded. They added this undocumented component through an unapproved procedure to mask or to hide the underlying degradation of the product. . . .
>
> You will first hear from Dr. Kevin Hicks, and he is the carbohydrate chemist. He is an expert on Lactulose, and he will tell you that Lactulose is a type of carbohydrate called a disaccharide, and this disaccharide degrades over time. And as time passes, the product breaks down into its component parts. **And you can detect this degradation of the product by testing its pH. And as the product degrades, the pH will decrease**. . . .
>
> In addition, another expert, Dr. John Senior, the gastroenterologist, will tell you . . . that if a product is sufficiently old and the disaccharide has degraded into its component products, the Lactulose simply will not work. The drug will

be ineffective in treating the patient's advanced liver disease.[4]

The government told the Seventh Circuit that it "did not dispute that before being spiked with sodium hydroxide [lots 52-230 and 52-231] were within the pH range, medically effective, and stable." Reply Brief of Appellant at 6. It told the jury that the Defendants injected sodium hydroxide "to mask or hide the underlying degradation of the product." Taking the government's representations at face value, the Seventh Circuit wrote, "In fact, the government did not argue that the Lactulose was unfit, or close to unfit." 175 F.3d at 578. After telling the jury that the lots were "degraded" before the addition of sodium hydroxide, in the next breath government counsel said, "if a product is sufficiently old and the disaccharide has degraded into its component products, the Lactulose simply will not work."

H. The Government Repeatedly Asked Its Lactulose Expert Whether A Decline In pH Indicated That The Product Had Degraded.

Government counsel asked their Lactulose expert, Dr. Kevin Hicks, the following questions:

> "As lactulose degrades, does the pH change? . . . Would the lowering of the pH o[f] the lactulose solution be indicative of degradation? . . . When lactulose is used as a pharmaceutical product is the expiration date reflective at all of the degradation process? . . . Would the addition of sodium hydroxide mask the degradation of the product if you were testing the pH? . . . Is the pH measure a measure-one

---

[4] Tr. 12/9/95 at 16, 20-21 (emphases added).

possible measure of the stability of a lactulose product? . . . What would the decrease in pH indicate relating to stability?. . . Would the addition of sodium hydroxide mask any degradation; that is, make it unable to discern degradation?"

Tr. 1582, 1587-89, 1597-1598, 1600-01.

On redirect of Dr. Hicks, government counsel elicited the following testimony:

Q. If you saw a product's pH drop over time from 5.4 to 3.4-and again we are talking about the data points on the stability study 87-227 comparing July '97 to February of '90-what would be the difference in the acidity? What percentage would that be?

A. From 5.4 to 3.2? 5.4 down to 3.2, is that what you are asking?

Q. 5.4 to let's stop at 3.4 for now.

A. To 3.4?

Q. Yes.

A. Again, you have a 100-fold difference.

Q. In a closed container would anything else other than the degradation of the lactulose explain a reduction in pH such as that?

A. Nothing that I am aware of.

> Q. Based on your experience, would you expect to see a reduction in the assay; that is, the percentage of lactulose, whenever you saw such a significant diminution or decrease in pH?
>
> A. There should be a decrease in the assay for lactulose.

Tr. 1652-53 (emphasis added).

Government counsel clearly intended to leave the jury with the impression that when Alra's Lactulose declined in pH to a level of 3.4 or lower, the assay for the active ingredient, or the measure of the product's medical effectiveness, would go down significantly. The post-trial discovery from FDA's files conclusively refuted that argument. That data showed that even when the pH declined below 3.0, the assay for the active ingredient remained unaffected. The government told the Seventh Circuit that "we never argued the material was decomposed due to its aging."

The government also intentionally left the jury with the impression that Lactulose was an unstable product, and that as its pH decreased, there would be a "cascading effect," or a precipitous decline in the product's effectiveness. Government counsel elicited the following testimony from Dr. Hicks:

> Dr. Hicks, are certain chemicals more stable than other chemicals?
>
> A. Certainly, yes.
>
> Q. Is lactulose a fairly stable or a very unfairly stable chemical?

A. Well, compared to other sugars, I would say it's relatively unstable. . . . .

Tr. 1575. Remember, the government told the Seventh Circuit that it never disputed that the Lactulose was "medically effective and stable."

Dr. Hicks went on to testify:

The degradation that you have been describing, is that a gradual or linear degradation or does it accelerate over time?

A. Well, I believe the initial stages would be relatively linear. If we think about the acid catalyzed degradation, what could happen is that since some of the breakdown products are acids themselves, that the pH of the solution or the acidity of the solution-let me just say the acidity of the solution will increase as the degradation occurs. So that could tend to make the degradation rate go faster with time.

Q. Are you familiar with the term "cascading effect."

A. Yes, I have heard that.

Q. Can you describe what that means?

A. Well, as I said, if you have a process that is regulated by the amount of acid, if the amount of acid is increasing in that system, then rather than getting a steady rate, the rate will increase. So there is a cascading or a snowballing type of an effect.

> Q. Would it be fair to say then that as the lactulose begins to degrade it will at first degrade slowly and then the degradation will speed up because there will be the presence of more acids which will cause in effect a snowball effect of a greater degradation?
>
> A. That makes sense in terms of chemical principles, yes.

Tr. 1580.

The government elicited testimony in front of the jury that Lactulose is unstable, that it had an expiration date of 18 months because it degraded over time, that the degradation would increase in a "cascading effect," and that the product would be ineffective in treating seriously ill patients if it was "degraded." The stability data in FDA's files directly contradicted all of these government arguments. After seeing the stability data from other manufacturers, the government turned 180 degrees and said to the Seventh Circuit that it never disputed that the Lactulose was "medically effective and stable," and said, "we never argued the material was decomposed due to its aging." The Seventh Circuit said "the government did not argue that the Lactulose was unfit, or close to unfit." 175 F.3d at 578.

Think about how different Dr. Hicks' testimony should have been if the government's representations to the Seventh Circuit about its trial theory were actually true. According to the government's new theory, Dr. Hicks should have been testifying that Lactulose is a stable drug. Dr. Hicks should have been testifying that Lactulose would not degrade in a

cascading effect. Dr. Hicks should have been testifying that three year-old lots with pH values that had declined by over 100-fold, would still be "medically effective and stable." Dr. Hicks never said that-the government elicited testimony that said just the opposite.[5]

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[5] The government has tried to salvage its trial strategy by claiming that it was arguing that adding sodium hydroxide would increase "degradation" of the product. That is not true; as this motion demonstrates, the government argued all along that lots 52-230 and 52-231 were degraded because of their age, and that Defendants added the sodium hydroxide to "mask" this "degradation." As further proof that the government's case was not based on "degradation" that would occur because of the addition of sodium hydroxide, here is what the government's own expert, Dr. Kevin Hicks, said at trial:

> Q. Thus, could adding sodium hydroxide accelerate, speed up, the degradation of lactulose in those bottles due to those pockets of sodium hydroxide?
>
> A. It's theoretically possible. It would be only localized into the regions where there would be a lot of sodium hydroxide and contact with a small amount of the sugar.
>
> Q. Would there be degradation in the remainder of the solution as well due to the addition of sodium hydroxide?
>
> A. Not if we are talking about just a localized event.

Tr. 11/22/95 at 61.

I. The Government Disputed Defense Expert Testimony That Lactulose Was Stable And That A Decline In pH Would Not Affect The Potency Of the Drug.

The defense called Dr. John F. Robyt, a professor of biochemistry at Iowa State University, as an expert witness. Tr. 4256. Dr. Robyt testified that the bond between the two sugars that form the Lactulose molecule (galactose and fructose) was "very strong." Tr. 4263. As the government is so fond of saying, Dr. Robyt testified that a decline in pH of Lactulose would indicate "degradation" of the active ingredient-he just didn't think that the "degradation" was more than a drop in the bucket. Dr. Robyt prepared a chart, Defendants' Exhibit R-2, which summarized his opinion about "the effect of the drop of pH from 7 to 3 on the amount of Lactulose that would be degraded in a Lactulose syrup." Tr. 4272. Government counsel objected four times to the admissibility of the exhibit. Tr. 4272, 4273, 4274, 4275. Dr. Robyt explained that if Lactulose Syrup was at a pH of 7, and contained 4,000,000 parts of Lactulose, a drop in pH from 7 to 6 would mean that only one part of Lactulose had degraded into one part of acid. "That would leave 3,999,999 parts of Lactulose remaining, and that was based on the composition of the Lactulose syrup and the pH. That would mean that the amount of Lactulose remaining was 99.999 percent." Tr. 4273. Dr. Robyt testified:

> If we go from pH 6 to pH 5, that would mean that there were ten parts of acid produced out of 4 million leaving 3,999,990 parts of Lactulose remaining. That would be 99.9997 percent Lactulose remaining.

> As we drop in pH further, pH 4, there are 100 parts of acid that has been produced out of 4 million parts.
>
> . . .
>
> Between gauge 6 and 3 Lactulose is very stable. It is insignificantly degraded as evidenced by a measurement of pH from 6 to 3 if pH is used as a means of measuring degradation.
>
> The thing about measuring pH is that it's an extremely sensitive method, and it is a change of 100 parts of acid from pH 6 to pH 4 that's for sure. But it's 100 parts of what? 100 parts of a very small number. And so, I say that from 6 to 3, Lactulose is very stable if that's what the pH is.

Tr. 4276-77.

Dr. Robyt also testified that if lots of Lactulose had been stored in bottles for two years, and then tested within specifications, the old lots would be "very, very similar, almost identical" to recently-manufactured lots. Tr. 4278. The stability data in FDA's files proved that Dr. Robyt was right, because it showed that Lactulose is stable as a rock for years, and that declines in pH do not affect the assay for the active ingredient.

According to the government's representations to the Seventh Circuit that the stability data in FDA's files was not material, that the government did not dispute that the old lots of Lactulose were "medically effective and stable," and that "we never argued the material was decomposed due to its aging," the government should have had no cross-examination

for Dr. Robyt. Government counsel should have said, "Dr. Robyt, we agree with everything you say," and sat down.

Instead, government counsel treated Dr. Robyt like the witness he was-a defense expert who was challenging the essence of the government's case. Government counsel challenged Dr. Robyt's qualifications on voir dire, trying to compare his lack of specific expertise on Lactulose with the expertise of the government's expert, Dr. Hicks:

> Q. Dr. Robyt, you indicated that you published approximately 130 articles; is that correct?
>
> A. Yes.
>
> Q. Are any of those articles on the sugar Lactulose? [Dr. Hicks had written articles on Lactulose.]
>
> A. No, they are not.
>
> Q. Have you conducted any laboratory work on the synthesis of Lactulose? [Dr. Hicks had developed a method for synthesizing Lactulose.]
>
> A. No.
>
> Q. Have you conducted any laboratory work on the degradation of Lactulose?
>
> A. No.
>
> Q. Have you conducted any laboratory work on the stability of Lactulose?

A. No.

Q. Have you received any professional awards relating to carbohydrate chemistry specifically Lactulose? [Dr. Hicks had received professional awards for his work on Lactulose.]

A. No.

Q. Have you ever presented papers relating to Lactulose? [Dr. Hicks had presented papers on Lactulose.]

A. No.

[Government counsel]: Your Honor, to the extent that the witness is being offered as an expert on Lactulose disaccharide, that type of sugar, we challenge him.[6]

After challenging Dr. Robyt's qualifications, government counsel asked him a number of questions trying to establish that Lactulose was "less stable" in a diluted liquid form:

Q. So even Lactulose in its pure crystalline form, 100 percent Lactulose, could under some conditions degrade?

---

[6] Tr. 4261-62. Government counsel's strategy worked, of course. The government's expert did have a better resume on Lactulose, and that resume carried the day at trial. That is why the stability data in FDA's files was so essential to the defense. With that data in the courtroom, the government's generalities about a decline in pH indicating "degradation" of Lactulose would have been revealed for the scientific folly they were.

A. Yep.

Q. Is that correct?

A. Yes.

Q. Now, if you take that solid and you put it in with a little bit of water, create a thick solution. The thicker the solution; that is, the less dilute the solution, the more stable it's going to be, correct?

A. Yes.

Q. So in 90 percent solution, that is a solution that contains 90 percent of pure Lactulose and ten percent something else. Let's say, water. It's going to be less stable than the crystalline form but still relatively stable. Would you agree with me?

A. It would be quite stable. It would be less stable. Well-

Q. Just a bit?

A. Just a tiny bit.

Q. And if you add more water, so now we have an 85 percent solution, it's going to be slightly less stable?

A. Yes.

Q. At 80 percent it's going to be slightly less stable, too?

A. Yes.

Q. 75 percent it's going to be slightly less stable still?

A. Yes.

Q. 70, even less stable?

A. Yes.

Q. Okay. Incrementally, 65 percent, it's going to be less stable?

A. Yes.

Q. 60 percent, less stable still?

A. You want to keep this up, sure. Yes.

Q. We will stop at some point, I assure you. 55 percent?

A. Yes.

Q. Let's talk about approximately a 50 percent solution?

A. Yes.

Q. Let's say you have lactulose that's mixed with approximately 50 percent of something else. You have a little bit of a breakdown of

> degrading products, and you have got some water. That's not going to be as stable as pure Lactulose, is it?
>
> A. No, but-

Tr. 4293-94. The Government told the Seventh Circuit that it did not dispute these lots were stable. Why was government counsel asking questions to establish that the lots were not stable?

Government counsel then used a certificate of analysis from the manufacturer that supplied Alra's lactulose concentrate, and pointed out that the raw material was approximately 50% water, and that it contained other sugars, such as lactose and galactose. Government counsel suggested that the presence of those other sugars could be by-products of degradation in the Lactulose that had already occurred. Tr. 4296-4302.

Government counsel also challenged Dr. Robyt's opinion that Lactulose would not degrade in a "cascading effect" when its pH approached 3:

> So the percentage of the Lactulose disaccharide over time will decrease, not linearly, but exponentially?
>
> A. If you have a cascading effect, yes.
>
> Q. And does Lactulose degrade in an acidic condition in a cascading effect?
>
> A. I don't think so.
>
> Q. Have you read any literature on that?

A. No.

Q. What's the basis of your opinion?

A. Well, a pH of 3, the amount of acid is very low and, therefore, I don't-I think you would still be in this part of the curve. And I don't know what happens when you get down to pH of 1 or 0. Indeed, that could be if you got to pH 1 or 0. It will go to 0. . . .

Q. Sir, you don't know that's what occurs at pH of 3, do you?

Tr. 4322.

During cross-examination of Dr. Robyt, government counsel also emphasized the government's theory of the case:

Q. Sir, would the increase of sodium hydroxide in any way reverse the degradation that we've been discussing? Put the Lactulose molecule back together again?

A. No.

Q. Would the decrease-the injection of sodium hydroxide in any way mask the degradation if I am measuring degradation by measuring pH?

A. Yes, of course.

Tr. 4331.

J. The Government Called A Gastroenterologist To Testify That "Degraded" Lactulose Could Kill Seriously Ill Patients.

After calling Dr. Hicks to testify that a decline in pH indicated that Lactulose had "degraded," the Government called Dr. John Senior, a gastroenterologist, to testify about the effect of "degraded" Lactulose. As this Court stated at a post-trial hearing on September 11, 1996:

> [o]ne of the most impressive witnesses at the trial, if not the most impressive witness, was the Government's expert, Dr. Senior. On page 27 of the transcript of his testimony, he is asked, I believe, by [Government counsel]: "Question: if Lactulose is degraded into monosaccharide components, would it work to treat portal systemic encephalopathy. Answer: No, it won't work if it is degraded or split because the split products of Lactulose are fructose and galactose which are easily absorbed sugars. They are gone. They never get to the colon." And he goes on in more detail on the following page, to talk about how if the Lactulose is degraded, it won't be medically effective. Then he is asked at line 17 of page 28: "Question: And would a physician be able to ascertain what was wrong if Lactulose had broken down into disaccharide forms?" Now, there would be absolutely no purpose in asking that question, it seems to me, unless the Government was contending that the question was relevant to the fact situation before the jury. The question addresses a situation where Lactulose had broken down into its [monosaccharide] form. And Dr. Senior, in what was, in my distinct recollection, an

> absolutely devastating answer said the following: "That makes it very hard on the physician because a lot is going on in these sick patients. They have got a failing liver. They often have. They are now getting failure of the brain function. They often have kidney failures that goes with the liver failures. They have got a lot of problems, and the last thing a physician is going to think of when he prescribes a drug is that it isn't what it is supposed to be." . . .
>
> Small wonder that the Court has a serious concern that, due to the tactics of the Government, the jury gained the impression that this Lactulose was dangerous to any patient who used it.

Motions hearing, 9/11/96 at 10-11 (emphasis added).

K. During Argument On Defendants' Rule 29 Motions, The Government Argued That The Lots Were "Decomposed To The Degree That [They] Could No Longer Be Used As A Medicine."

On January 24, 1996, during oral argument on Defendants' Rule 29 motion, government counsel told this Court that "[t]he easiest indicator of deterioration is the reduction in the pH . . . ." Tr. 1/24/96 at 125. Government counsel told the Court that "the sodium hydroxide addition . . . would mask the degradation." Tr. 1/24/96 at 126. Government counsel told the Court, "what Dr. Hicks testified to that the product was decomposing-the testimony of Dr. Hicks was that that was evidence that the drop in pH was evidence of the decomposition, and that, with regard to the expiration date, the government's theory as was added to mask that." Tr. 1/24/96

at 148. Government counsel told this Court during Rule 29 argument, "as Dr. Hicks testified, the product will degrade over time, and after 18 months the product would have degraded to such a point that it would not longer be appropriate for use as a medicine . . . ." Tr. 1/24/96 at 149.

During Rule 29 argument, this Court said, "Well, what we are talking about here is a problem with tense, I think. Count 3, just, for example, talks about something [the alleged addition of sodium hydroxide] that was done on or about August 12, 1988. And it talks about a decomposed substance as of that date. You are talking about something that may have happened in the future after August 12th." Government counsel responded, "No, your Honor. As of August 12th, 1988, when they were packaging this product for resale, we had a product that had been manufactured in, I believe it was either December of 1985 or January of 1986. That is when the raw material had been manufactured; that that material, according to the testimony of Dr. Hicks, would begin to decompose as of its time of manufacture and it's either December of '85 or January of '86; that the expiration date based on the testing that had been done and the literature was that Lactulose by 18 months after its manufacture would be decomposed to the degree that it could no longer be used as a medicine." Tr. 1/24/96 at 150 (emphasis added).

L. The Government Attacked The Testimony Of A Chemist Who Tested Alra's Reserve Samples Of Lactulose And Found Them All Within Specification For Potency Years After Manufacture, And Even Though The pH Of The Lots Had Declined.

At trial, the defense called Dr. Sneh Bhandari, a Ph.D chemist, who tested retained samples of Lactulose lots 52-230 and 52-231, and samples from other Alra lots, during the trial.

Although lots 52-230 and 52-231 were ten years old, and their pH values had dropped below 3, both lots tested above 100% for label claim of Lactulose content. Tr. 2/5/96 at 3-8.

According to the government's representations to the Seventh Circuit, this testimony should have been non-controversial, since the government now claims that it "did not dispute" that the lots were "medically effective and stable." Government counsel did not treat the testimony as non-controversial. Instead, government counsel repeated the theory that a decline in pH was evidence of "degradation." "And the degradation of the product with organic acids as a by-product could explain that increase in acid formation which corresponds to a decrease in pH; is that right?" Tr. 2/5/96 at 16. Government counsel challenged Dr. Bhandari's expertise- "Your laboratory typically does food and vitamin testing; isn't that right? . . . You don't do much Lactulose testing or drug testing; isn't that right?" Tr. 2/5/96 at 17.

Finally, government counsel suggested to the jury that Defendants had tampered with the samples: "you have no idea what's happened to these bottles between 1988 and 1996, particularly January 30th of 1996, do you?" Tr. 2/5/96 at 18.

M. The Defendants Testified That They Had No Reason To Increase The pH Of The Lactulose, And The Government Attacked Their Credibility

Defendant Neelam Bhutani testified in her own defense. She said that in early August, 1988, her laboratory tested lots 52-230 and 52-231. Government Exhibit 100 showed that Alra tested two samples from lot 52-230, and got pH results of 5.3 and 5.4. Government Exhibit 101 showed that Alra tested two samples from lot 52-231, and got pH results of 5.6 and 5.3. Tr. 1/30/96 at 84-87. On direct, her counsel asked, "Based on that

information, can you think of any reason why the pH of these lots would then be adjusted within a week after the testing?" She answered, "No, I can't think of any reason." Tr. 1/30/96 at 87. Mrs. Bhutani denied having any knowledge that Alra employees had injected any substance into lots 52-230 and 52-231. Tr. 1/30/96 at 87-88.

During cross, government counsel asked Mrs. Bhutani to confirm that she knew FDA had set an 18-month expiration date on Alra's Lactulose. Tr. 1/31/96 at 159-60. Government counsel cross-examined Mrs. Bhutani at length about the age of the raw material that had gone into lots 52-230 and 52-231:

> Q. Will you agree with me then that the [raw material of the Lactulose] product would have to have been manufactured some time before January 14th of 1986?
>
> A. Yes.
>
> Q. So as of the time these two lots were released in August of 1988, this material had existed throughout 1986, 1987, and seven months of 1988, correct?
>
> A. Yes.
>
> Q. And in addition, it was given an expiration date until September of 1989?
>
> A. Yes.
>
> Q. Correct? So at this point in time, depending on when this product was actually made, by the time the product, 52-230 and 52-231, reached its expiration date of September 1989, is it not

accurate that the raw material had been manufactured at least 45 months earlier?

A. Probably.

Q. Well, is there any doubt in your mind?

A. '89 to '86-maybe 42. Yes, if the math is right, I am not going to-

Q. Now, at this point in time, the time that you released the product, August of 1988-

A. Yes.

Q. -the position of the FDA was that Alra had submitted data, had data that would support an expiration date of up to 18 months, correct?

A. I have no knowledge of what was submitted to FDA. What I had with me, I can testify to that because I did not deal with FDA at all.

Q. Okay. But you wrote to Searle telling them that it was 18 months from the date of manufacture of the raw material, correct?

A. Yes.

Q. And is it not true that Alra, throughout this time period, 1989, 1990, 1991, 1992, was requesting an extension in the expiration date from 18 to 24 months on its Lactulose?

A. Yes.

Q. And isn't it true that the FDA was denying this request?

A. I told you I am not involved in dealing with FDA. I was not. I don't know what they were doing, denying or they were requesting or what they were doing. I had no knowledge of those dealings.

Q. At the time the product was released in August of 1988, the time you signed off on it-

A. Yes.

Q. -you had no data whatsoever with regard to the stability of Lactulose for a period beyond the then current age of this product, did you?

A. We had 40 degree stability data on one of the lots for six months and -

Q. You had 40 degree stability data on ne of the lots in 1989, ma'am?

Tr. 1/31/96 at 165-67.

At trial, the government attacked Mrs. Bhutani's credibility, suggesting in repeated questioning that she knew, or should have known, that the product was not stable when it was released. Think about how different that cross would have been if government counsel had said, "Mrs. Bhutani, you were right, that product was 'medically effective and stable.' But then you added sodium hydroxide bottle-by-bottle (for no reason that we discern) and that made the product dangerous, right?"

Dr. Raj Bhutani testified in his own defense. He testified that when he got the lab results on lots 52-230 and 52-231, there was no reason to doctor or fix the batches in any way: "It had almost hundred percent of its potency. It was--microbiologically, it was pure. pH was in good range. Physical inspection was pretty good. No, there was no reason whatsoever." Tr. 1/31/96 at 22-23. Dr. Bhutani also testified that based on his experience with Lactulose, and based on stressed stability testing Alra had done at high temperatures, he believed the lots were stable, even though they had been manufactured in 1986. Tr. 1/31/96 at 26-27. Dr. Bhutani testified that "There was absolutely no reason" for him to instruct his employees to inject sodium hydroxide into lots 52-230 and 52-231. Tr. 1/31/96 at 27.

Government counsel cross-examined Dr. Bhutani about the defense assertion that the Lactulose was stable even though it was several years old. Dr. Bhutani relied on stability tests Alra had performed on several research and development batches of Lactulose. Government counsel asked repeated questions about the size of Alra's research and development batches of Lactulose, which were generally two liters in size. Tr. 2/5/96 at 185-88. Government counsel specifically asked, "Other than making these small batches of under a gallon, what other research and development work did you do with regard to Lactulose prior to the time that you made lots 52-230 and 52-231?" Tr. 2/5/96 at 187.

N. During Closing Argument, Government Counsel Argued That Lots 52-230 And 52-231 Were "Degraded," That Defendants Added Sodium Hydroxide To "Mask" That "Degradation," And That "Degraded" Lactulose Might Kill Seriously Ill Patients.

In closing argument, Government counsel repeated the argument that a decline in pH meant that the Lactulose had degraded, and that the "degraded" Lactulose sold by the Defendants may have killed patients:

> Now, after you heard about all the chemistry, you heard from a physician, and that was Dr. John Senior. **And he told you the medical consequences of this degradation and why in very human terms this all matters.** . . .
>
> But as Dr. Senior pointed out, the Lactulose has to reach the large intestine in order for it to work. If the Lactulose is already broken down, **if it is already degraded** into its monosaccharide form, the monosaccharides will be absorbed in the small intestine, they'll be digested and the Lactulose in its disaccharide form will never reach the colon, the site of the effective treatment. And it will be rendered ineffective in treating patients with hepatic coma or portal systemic encephalopathy.

Memorandum Opinion of the Honorable John F. Grady, December 17, 1997, quoting Government's first closing argument (emphases added).

Both Government counsel also argued that the motive for adding sodium hydroxide to lots 52-230 and 52-231 was to mask the "degradation" of those lots:

> They did this to make sure that if anyone tested the pH of the drug product, it would test high. They wouldn't know it was old, they wouldn't know it had degraded. They did this so the consumers couldn't know of the truth about the products that they were buying. They wouldn't know the pH had dropped, they couldn't tell the product had degraded, and they wouldn't suspect that it had passed the expiration date.

Tr. 5585 (first closing).

> They raised the sodium hydroxide, so if three months or six months down the road AARP or - I forgot the other company they sold this to - Bioline I think it was, checked the pH, it would appear that this stuff was new. It didn't just have to be within spec, it had to be new because this stuff was labeled with a September of 1989 expiration date.

Tr. 5805 (rebuttal closing).

Think about how different the closing arguments would have been if government counsel had told the jury, "They injected a chemical into lots that were 'within the approved pH range, medically effective, and stable.'" Government's Reply Brief at 6. If the jury had heard an

argument like that, would it have found that the Defendants had a motive to add the sodium hydroxide?[7]

O. In Post-Trial Submissions To The Probation Department, The Government Argued That A Decline In pH Evidenced "Degradation."

In its April 22, 1996 submissions to the Probation Officer, the government wrote: "If the lactulose degrades and fails to reach the colon in its original form, it is rendered ineffective . . . . The degradation of the product is evidenced by a decrease in the pH . . . ." April 22, 1996, letter re Neelam Bhutani to Ms. Elisa J. Ehrlich, at 7.

P. The Government's Opposition To Post-Trial Discovery Restated The Government's Theory Of Motive.

After the government submitted its Version of the Offense to the Probation Department in 1996, the United States Pharmacopeia ("USP") proposed a downward revision of the acceptable pH range for Lactulose, from 3.0 - 7.0 to 2.5 - 6.5. The USP proposal stated:

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[7] To the extent that the Seventh Circuit relied on the government's theory that ALRA had placed "inaccurate expiration date[s]" on the Lactulose lots, the Government's first witness, Dr. Eric Duffy, a Ph.D review chemist employed by FDA, conceded that one of several reasonable interpretations of Dr. Bhutani's correspondence with the FDA was that Alra was allowed to sell "old" lots of Lactulose it had on hand based on passing final lab testing of the product. Tr. 333-35. The jury acquitted defendants on counts 2 and 5, which alleged that the Lactulose lots had been labeled with inaccurate expiration dates.

> [b]ased on information received that stability data has shown a downward trend in pH over time, it is proposed to revise the pH range in this monograph. The proposed pH change is reported not to have any significant impact on the safety and quality of this product: it does not in any way affect the laxative properties of the product, and it does not affect the level of the related substances.

J.A. 284-85.

Defendants moved for a new trial and for discovery of Lactulose stability data in FDA's files consistent with the USP proposal. The district court ordered discovery. The government opposed the motion for trial, arguing, among other things, that the defense should have subpoenaed stability data because the government had notified the defense of its theories concerning the relevance of pH data on Lactulose. The government's opposition argued that declining pH values in Alra's stability data

> was thus relevant to establish Defendants' motive in injecting sodium hydroxide into the old Lactulose before releasing it on the market. The declining pH indicated the Lactulose was degrading and would be past its expiration date, so the Defendants ordered the injection of a base (sodium hydroxide) to mask the fact that the product was old and had passed its expiration date.

Government's Opposition to Defendants' Post-Trial Motion for a New Trial Based on Newly Discovered Lactulose Stability Evidence, served June 12, 1997, at 14 & n.8 (emphasis added). How does the statement that the "declining pH indicated the

Lactulose was degrading and would be past its expiration date" square with the representation to the Seventh Circuit that the government "did not dispute" that the Lactulose was "medically effective and stable" before the alleged addition of sodium hydroxide? How does the statement that "the product was old and had passed its expiration date" square with the representation that "we never argued the material was decomposed due to its aging?"

III. A COMPARISON OF THE GOVERNMENT'S "VERSION OF THE OFFENSE" BEFORE AND AFTER TRIAL DRAMATICALLY ILLUSTRATES THE GOVERNMENT'S CHANGE OF POSITION.

In 1996, before the district court ordered discovery of the stability data in FDA's files, the government had submitted a "Government's Version of the Offense" to the Probation Department. The government recently submitted a Sentencing Memorandum to the district court in preparation for a sentencing hearing scheduled for January 11, 2000. Government counsel edited the 1996 version of the "Government's Version of the Offense" in a telling way.

The 1996 version contained the following paragraph:

> Because Lactulose degrades, it loses its therapeutic efficacy over time. The degradation of the product is evidenced by a decrease in the pH (or rise in acidity) of the finished product. If sodium hydroxide (a base) is added to Lactulose, the pH will rise, but the degradation will not be reversed. Accordingly, injecting sodium hydroxide into finished bottles of Lactulose will simply serve to mask the degradation of the product.

Note how this 1996 "Government's Version of the Offense" contradicts the representations made to the Seventh Circuit. This 1996 version does not say that the Lactulose was "medically effective and stable" before the addition of sodium hydroxide; it says that the addition of sodium hydroxide "will simply serve to mask the degradation of the product."

For the 1999 "Government's Version of the Offense," counsel edited that paragraph to read:

> Because Lactulose, like all other chemicals, degrades, it will necessarily lose its therapeutic efficacy over time. The only way to know the rate at which any particular formulation of Lactulose Syrup, U.S.P., will degrade, and thereby to know for how long it will retain its therapeutic effectiveness, would be to test it over time.

What happened to "masking the degradation?"

CONCLUSION

Defendants respectfully request that the Department of Justice re-examine its conduct in this case, and confess error in response to the Petition for Certiorari currently pending before the Supreme Court.

Very truly yours,

Christopher B. Mead

London & Mead
1225 19th St., N.W., 7th Floor
Washington, D.C. 20036

January 11, 2000

Lawrence G. McDade
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
(By telecopy to 202/514-8742)

Deborah S. Smolover
Counsel to the Deputy Attorney General
U.S. Department of Justice
950 Pennsylvania Ave., N.W.
Washington, D.C. 20530
(By telecopy to 202/616-1239)

Douglas N. Letter
Robert M. Loeb
Attorneys, Appellate Staff
U.S. Department of Justice
Room 9136 PHB
601 D St., N.W.
Washington, D.C. 20530-0001
(By telecopy to 202/514-8151)

Re: United States v. Bhutani, et al.

Dear Counsel:

Thank you for your courtesy and patience yesterday. I realize that because I got emotional and frustrated, I was less articulate, and less polite, than I would like to be. I remain convinced that the Department of Justice has a fundamental misunderstanding of what happened in this case. I hope that the letter I left with you yesterday shows you why I feel so strongly. I am writing this second letter as an additional attempt at persuasion.

During the meeting with Doug, Larry, and Bob yesterday, Bob recalled that a jury instruction had made reference to "degradation." Bob suggested that this jury instruction showed that the government had not contended

that Lactulose lots 52-230 and 52-231 were unstable or ineffective prior to the alleged addition of sodium hydroxide. The jury instruction that Bob was remembering defined "decomposed substances," not "degradation," and conclusively demonstrates that the government contended that lots 52-230 and 52-231 were medically ineffective prior to the alleged addition of sodium hydroxide. The Indictment and the government's requested jury instructions show that the government presented a theory of conviction that lots 52-230 and 52-231 were "adulterated" because they were composed of a "decomposed substance." The government agreed to a jury instruction that a "decomposed substance" meant that "the Lactulose active ingredient had decomposed so that it no longer met applicable testing specifications . . . ."

Overt Act 2 in the conspiracy count alleged: "BALDEV RAJ BHUTANI and NEELAM BHUTANI directed ALRA employees to add an undocumented substance, namely additional amounts of Sodium Hydroxide (NaOH), to partially decomposed Lactulose in the finished generic drug product Lactulose Syrup, USP . . . ." (Emphasis added).

Count 3 of the Indictment alleged that lot 52-230 was adulterated on August 12, 1998 in three separate ways: "(1) this drug product consisted in part of a decomposed substance, namely decomposed lactulose raw material; (2) the drug product had not been manufactured in accordance with Good Manufacturing Practice; and (3) the defendants materially altered the manufacturing procedures for this drug product by adding an undocumented substance, Sodium Hydroxide . . . ."

It is clear from Overt Act 2 and the date of adulteration in Count 3 (the date of the alleged rework), that the government contended that the product consisted of a "decomposed substance" prior to the alleged addition of sodium hydroxide. Government's Requested Jury Instruction No. 44 read:

DEFINITION OF "ADULTERATION"
(IN CONTEXT OF COUNT THREE)

. . .

You may find that this particular lot of Lactulose was "adulterated" in one of three ways.

First, Count Three alleges that Lactulose lot 52-230-P was adulterated in that this drug product consisted in part of a decomposed substance, namely decomposed Lactulose raw material. If you unanimously find this to be the case, you should find this lot of Lactulose "adulterated."

Second, Count Three alleges that Lactulose lot 52-230-P was adulterated in that the defendants materially altered the manufacturing procedures for this drug product by adding an undocumented substance, Sodium Hydroxide, more than two years after the original manufacture of this drug product. If you unanimously find this to be the case, you should find this lot of Lactulose "adulterated."

Third, Count Three alleges that Lactulose lot 52-230-P was adulterated in that the drug product had not been manufactured in accordance with Good Manufacturing Practices. . . .

Judge Grady read this instruction to the jury. Tr. 5840-41.

The government agreed to a modified version of Alra Requested Instruction No. 4, which provided:

> In Counts Three, Six, Seven, and Eight, the government alleges that certain raw material or finished product lots of Lactulose were "decomposed." For purposes of these counts, "decomposed" means more than that the Lactulose active ingredient had begun to degrade; all drug products begin a degradation process to a greater or lesser degree after manufacture. The government must prove beyond a reasonable doubt that at or about the time alleged in the particular count the Lactulose active ingredient had decomposed so that it no longer met applicable testing specifications in order for you to find that the Lactulose lots specified in Counts Three, Six, Seven, and Eight were "decomposed."

(Emphasis added). Judge Grady read this instruction to the jury. Tr. 5842.

Following the government's proposed jury instructions, the jury may have voted to convict on Count 1, the conspiracy, based on Overt Act 2, which alleged that Defendants added sodium hydroxide to a "decomposed substance," defined as "decomposed so that it no longer met applicable testing specifications." The jury may have voted to convict on Count 3 based on the government's theory that lot 52-230 was adulterated because it "consisted in part of a decomposed substance," defined as "decomposed so that it no longer met applicable testing specifications."

The government's theories of conviction on Counts 1 and 3 alone conclusively demonstrate that the government contended the lots were not medically effective and stable. The representations to the Seventh Circuit that the government "did not dispute that before being spiked with sodium hydroxide [lots 52-230 and 52-231] were within the pH range,

medically effective, and stable," and "we never argued the material was decomposed due to its aging" were thus clearly wrong. So was the Seventh Circuit's opinion, parroting the representations of the government, that "the government did not argue that the Lactulose was unfit, or close to unfit." 175 F.3d at 578.

The government told the Seventh Circuit that it never disputed that the lots were "stable." Government counsel told the jury something different in closing argument: "Dr. Hicks explained how Lactulose is an unstable sugar. It breaks down easily. And what that basically means, it degrades." Smolover closing at 36.

Government counsel's Rule 29 argument to the district court also directly contradicted the representations to the Seventh Circuit that the government "did not dispute that before being spiked with sodium hydroxide [lots 52-230 and 52-231] were within the pH range, medically effective, and stable," and "we never argued the material was decomposed due to its aging." Government counsel told the district court during Rule 29 argument, "as Dr. Hicks testified, the product will degrade over time, and after 18 months the product would have degraded to such a point that it would not longer be appropriate for use as a medicine .... Lactulose by 18 months after its manufacture would be decomposed to the degree that it could no longer be used as a medicine." Tr. 1/24/96 at 149-50.

Bob suggested that because this Rule 29 argument did not occur in front of the jury, the representations to the Seventh Circuit were still accurate. That position is untenable. You did not qualify the representations to the Seventh Circuit by saying that government counsel presented one theory to the district court, but a different theory to the jury. Even more important, government counsel's Rule 29 arguments illustrate government counsel's understanding, during the trial, of what the government's arguments to the jury meant. We have

argued that in the context of the trial, the government's use of the word "degradation" conveyed a very clear impression to the jury that the product was ineffective and unstable. Ask anyone what a "degraded" or "expired" product is, and I doubt if you would hear anyone say it means a product that is "medically effective and stable." References to "degradation" as a continuous process do not mean that references to "degraded" or "expired" product would be understood by a jury of laypersons to mean "medically effective and stable." If you simply read the quotations in Judge Grady's opinion, and substitute the phrase "old, but medically effective and stable" every time government counsel used the word "degraded," "degradation," or "expired," you will see that the meaning and emphasis and jury appeal of the government's arguments would be quite different. It's not sexy to argue to a jury that the lots were "medically effective and stable," and that the government wants to put people in jail for not honoring an expiration date that did not affect the quality of the product.

At the meeting, you seemed to contend that the government's trial theory was that a decline in pH evidenced "degradation" that had no correlation to the medical effectiveness, and that all of the government's references to "degradation" simply referred to the aging of a product that had passed its expiration date. Why didn't the government tell the jury that? If that was my theory, I would argue to the jury that "a decline in pH reflects that the product was aging, even though the pH may not correlate to the medical effectiveness of the product. To mask the age of the product, the defendants added sodium hydroxide to raise the pH." Instead, government counsel told the jury:

> The defendants instructed their employees to open up the bottles of Lactulose, those 1986 bottles, and inject a chemical called sodium hydroxide into the bottles in order to raise the pH and make it appear that the

product had not, in fact, degraded. They added this undocumented component through an unapproved procedure to mask or to hide the underlying degradation of the product. . . .

You will first hear from Dr. Kevin Hicks, and he is the carbohydrate chemist. He is an expert on Lactulose, and he will tell you that Lactulose is a type of carbohydrate called a disaccharide, and this disaccharide degrades over time. And as time passes, the product breaks down into its component parts. **And you can detect this degradation of the product by testing its pH. And as the product degrades, the pH will decrease. . . .**

In addition, another expert, Dr. John Senior, the gastroenterologist, will tell you . . . that if a product is sufficiently old and the disaccharide has degraded into its component products, the Lactulose simply will not work. The drug will be ineffective in treating the patient's advanced liver disease.[1]

. . .

Now, after you heard about all the chemistry, you heard from a physician, and that was Dr. John Senior. **And he told you the medical consequences of this degradation and why in very human terms this all matters. . . .**

But as Dr. Senior pointed out, the Lactulose has to reach the large intestine in order for it to work. If the Lactulose is already broken down, if it is already degraded into its monosaccharide form, the monosaccharides

---

[1] Tr. 12/9/95 at 16, 20-21 (emphases added).

> will be absorbed in the small intestine, they'll be digested and the Lactulose in its disaccharide form will never reach the colon, the site of the effective treatment. And it will be rendered ineffective in treating patients with hepatic coma or portal systemic encephalopathy.

Smolover closing at 40-41 (emphases added).

You can't tell a jury that "degraded" Lactulose will kill patients, tell the jury that Alra's Lactulose was "degraded," and then tell the Seventh Circuit that the government "did not dispute that before being spiked with sodium hydroxide [lots 52-230 and 52-231] were within the pH range, medically effective, and stable," and "we never argued the material was decomposed due to its aging."

The government repeatedly contended that Judge Grady had not reviewed the record carefully, and had an incorrect memory of the government's trial arguments. To the contrary, Judge Grady carefully considered the government's arguments and the trial record. Judge Grady was far more articulate than I was about the context in which the government used the word "degradation." At a post-trial hearing on September 11, 1996, Judge Grady said:

> The government denies that it ever said or implied that the degree of degradation reached by the two lots in question presented a danger to the user.

I have a very substantial question in my mind as to whether the government's position is supported by the record. First of all, there is the common sense proposition that degradation that has not reached the dangerous level and, in fact, is remote from a dangerous level would not be the subject of the constant repetition it received during this trial.

In Miss Smolover's opening statement, I don't know how many times-and I don't have the whole opening statement; I just have an excerpt from it-I don't know how many times she mentioned the word or used the word "degradation" or "degrade." And it is at the moment impossible for me to read that opening statement without concluding that she was saying that this was a dangerous situation because the Lactulose had degraded and that the defendants attempted to mask that degradation by changing the pH, the only index that someone would have, to determine whether, in fact, there had been degradation.

There is a particular reference at page 16 of the transcript where Miss Smolover said the following in her opening statement to the jury, beginning at line 7:

"That is not all they did. Before they shipped the product our the door, they took another important step to cover up the fact that they were shipping expired product. Oftentimes large buyers or wholesalers of generic drug products will test a product once it has been received and they will test a product like Lactulose for something like pH or acidity,

and those tests are designed to assure that the product is not degrading, that it is still within specification."

Now, I emphasize the phrase, "still within specification." Miss Smolover is saying that the test for pH would determine whether the product was still within specification, and specification would be 3 to 7.

She goes on to say:

"Baldev Raj Bhutani and Neelam Bhutani knew this. In fact, Alra was selling these products to large pharmaceutical wholesalers including the AARP and Biolab. So what did the Bhutanis do? The defendants instructed their employees to open up the bottles of Lactulose," and so on.

The next paragraph:

"They added this undocumented component through an unapproved procedure to mask or hide the underlying degradation of the product."

Now, it is difficult for me to read that language without having the impression that degradation and falling below specifications are one and the same and that the purpose of the addition of the pH was to mask the fact that the product fell below specification.

One of the most impressive witnesses at the trial, if not the most impressive witness, was the Government's expert, Dr. Senior. On page 27 of the transcript of his testimony, he is asked, I believe, by Miss Smolover:

"Q if Lactulose is degraded into monosaccharide components, would it work to treat portal systemic encephalopathy?

"A No, it won't work if it is degraded or split because the split products of Lactulose are fructose and galactose which are easily absorbed sugars. They are gone. They never get to the colon."

And he goes on in more detail on the following page, to talk about how if the Lactulose is degraded, it won't be medically effective. Then he is asked at line 17 of page 28:

"Q And would a physician be able to ascertain what was wrong if Lactulose had broken down into disaccharide forms?"

Now, there would be absolutely no purpose in asking that question, it seems to me, unless the Government was contending that the question was relevant to the fact situation before the jury. The question addresses a situation where Lactulose had broken down into its [monosaccharide] form.

And Dr. Senior, in what was, in my distinct recollection, an absolutely devastating answer said the following:

"That makes it very hard on the physician because a lot is going on in these sick patients. They have got a failing liver. They often have. They are now getting failure of the brain function. They often have kidney failures that goes with the liver failures. They have got a lot of problems, and the last thing a physician is going to think of when he prescribes a drug is that it isn't what it is supposed to be."

Now, the government knew what the answer was going to be, and the answer was either relevant to the case before the jury or it wasn't. And if we weren't dealing with a situation where, unbeknownst to the physician and the patient, the Lactulose wasn't going to get through to the colon, that answer should not have been elicited from that witness.

Small wonder that the Court has a serious concern that, due to the tactics of the Government, the jury gained the impression that this Lactulose was dangerous to any patient who used it.

Now, turning to Miss Smolover's closing argument, and referring to page 40 of the transcript, at line 6:

"Now, after you heard about all the chemistry, you heard from a physician, and that was Dr. John Senior, and he told you the medical consequences of this degradation and why, in very human terms, this all matters."

What does the phrase "this degradation" refer to? Well, the immediately

> preceding paragraph referred to the very Lactulose involved in the two lots in this case where Miss Smolover said:
>
> "The chemical is injected to hide the declining pH. It didn't make the product whole again"-note the verb "didn't," referring to the very events in this case-"it didn't make the product whole again; it didn't reverse the degradation. In fact, it sped it up."
>
> And then immediately following we have the reference to the testimony of Dr. Senior concerning the medical consequences of this degradation. . . .

Motions hearing, 9/11/96 at 8-12 (emphasis added).

I am also unsure of Bob's understanding of what "stable" means. The government contended throughout the trial that lots 52-230 and 52-231 should not have been sold because they were already inappropriate for use as medicine, and because there was no data to establish that the lots would remain potent through the expiration period stamped on the bottles. The defense argued that Lactulose was stable as a rock, and that the lots would remain effective for years after the expiration date stamped on the bottles. The stability data in FDA's files demonstrated that the defense was right. That's why Judge Grady thought the stability data was helpful to the defense and material. I got the impression from our meeting that Bob thinks "stable" means within specifications today, even if it may go out of specification tomorrow. That is not what any participant at trial would understand the word "stable" to mean. As the jury was told repeatedly by FDA witnesses, "stability" studies are tests designed to ensure the potency of the product throughout its shelf life, not just on the date of its release. The Seventh Circuit understood the

government's representations to mean that "the government did not argue that the Lactulose was unfit, or close to unfit." 175 F.3d at 578 (emphasis added).

Government counsel did not tell the jury that Lactulose was "stable." They said just the opposite. In addition to saying, "Lactulose is an unstable sugar. It breaks down easily,"[2] Deborah told the jury in closing argument:

> And it's because lactulose degrades, it's because Lactulose does not remain stable over time, that it's given an expiration period by the FDA.
>
> Now, Dr. Hicks further explained that this degradation process is not linear. It accelerates, cascades or snowballs, and that that happens all the time. It begins happening the moment that the Lactulose is synthesized into a liquid, into that concentrate syrup in those drums. And it continues to degrade once it's formulated into its finished product form. Even when it is within USP specifications, even when it's in the specifications of pH 3 to 7, it's constantly degrading into its component parts, and that degradation speeds up.
>
> And most importantly what Dr. Hicks told you is that degradation process cannot be reversed. It can't be stopped. But it can be hidden. The truth can be masked. And Dr. Hicks told you how the truth can be masked.
>
> He explained the effect of adding the base sodium hydroxide to individual bottles of

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[2] Smolover closing at 36.

> Lactulose. He told you of the very important scientific fact that sodium hydroxide, a base, will raise the pH in those bottles and mask the evidence that the product has degraded. It will not put the Lactulose molecules back together, again, but it will hide the fact that they've come apart.

Smolover closing at 37-38. Is that a description of a "medically effective and stable" product? Is that a description of a product that the government "never argued . . . was decomposed due to its aging?"

The government alleged that lots 52-230 and 52-231 consisted of decomposed substances before the alleged rework, and agreed with a jury instruction that a decomposed substance meant that the active ingredient was "decomposed so that it no longer met applicable testing specifications . . . ." Tr. 5842. The government told the district court, "as Dr. Hicks testified, the product will degrade over time, and after 18 months the product would have degraded to such a point that it would not longer be appropriate for use as a medicine . . . . Lactulose by 18 months after its manufacture would be decomposed to the degree that it could no longer be used as a medicine." Tr. 1/24/96 at 149-50 (emphasis added). Government counsel told the jury, "Lactulose is an unstable sugar. It breaks down easily. And what that basically means, it degrades." The government told the jury over and over again that the lots were "degraded" and "expired," and called a gastroenterologist to say that "degraded" Lactulose might kill seriously ill patients. The government told the Seventh Circuit that it "did not dispute that before being spiked with sodium hydroxide [lots 52-230 and 52-231] were within the pH range, medically effective, and stable," and "we never argued the material was decomposed due to its aging."

The words "degraded," "decomposition," and

"expired" have well-understood meanings. They do not mean "medically effective and stable." They do not mean different things on different days to different audiences.

My clients are counting on you to do the right thing. We would appreciate a response to my letters by Monday, January 17.

Very truly yours,

Christopher B. Mead

Supreme Court, U.S.
FILED
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No. 01-1188

In the Supreme Court of the United States

BALDEV RAJ BHUTANI, AND
ALRA LABORATORIES, INC., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

THEODORE B. OLSON
Solicitor General
Counsel of Record

ROBERT D. MCCALLUM, JR.
Assistant Attorney General

DOUGLAS N. LETTER
ROBERT M. LOEB
LAWRENCE G. MCDADE
Attorneys

Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

QUESTIONS PRESENTED

1. Whether the district court committed reversible error in its instructions on proof of materiality under 21 U.S.C. 333(a)(2).

2. Whether petitioners' failure to maintain records as required by 21 U.S.C. 355(k) served as a valid basis for a conviction under 21 U.S.C. 333(a)(2).

3. Whether the district court's use of Sentencing Guidelines (Guidelines) § 2F1.1 violated the Ex Post Facto Clause.

4. Whether the evidence was sufficient to sustain petitioners' convictions for distributing contaminated Lactulose from leaking drums.

5. Whether the district court correctly determined that there was a fraud loss under Guidelines § 2F1.1.

6. Whether the court of appeals erred in determining that there was no inconsistency between the government's position on appeal and its position at trial.

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In the Supreme Court of the United States

No. 01-1188

BALDEV RAJ BHUTANI, AND
ALRA LABORATORIES, INC., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-15) is reported at 266 F.3d 661. The opinion of the district court (Pet. App. 18-19) is unreported. An earlier opinion of the court of appeals (Pet. App. 22-35) is reported at 175 F.3d 572. An earlier opinion of the district court (Pet. App. 36-66) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on September 12, 2001. A petition for rehearing was denied on November 14, 2001 (Pet. App. 17). The petition for a writ of certiorari was filed on February 12, 2002. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Following a jury trial in the United States District Court for the Northern District of Illinois, petitioners Bhutani and Alra Laboratories, Inc. were convicted of adulterating the drug Lactulose by adding sodium hydroxide (Count 3), failing to record the addition of the sodium hydroxide (Count 4), and distributing the adulterated Lactulose (Count 6). In addition, petitioners were convicted of distributing the drug "K+10" after it was contaminated with metal shards (Count 10), and using contaminated Lactulose concentrate as a drug ingredient and then selling the contaminated drug (Counts 7 and 8). Finally, petitioners were convicted of a conspiracy to commit the above substantive offenses (Count 1).

The district court granted petitioners' motion for a new trial. The court of appeals reversed and remanded for sentencing. The district court sentenced petitioner Bhutani to 30 months' imprisonment and fined both petitioners. The court of appeals affirmed.

2. Petitioner Bhutani is the owner of petitioner Alra Laboratories, Inc. (Alra), a pharmaceutical company. Pet. App. 23. Alra produces generic drugs, including Lactulose, a drug that combats liver disease, and K+10, a potassium supplement. *Ibid.*

The government's evidence at trial established that Bhutani directed his employees to spike two lots of Lactulose with sodium hydroxide in order to conceal the age of those lots. Pet. App. 25. In response to Bhutani's directions, employees opened bottles of Lactulose, spiked them with sodium hydroxide, resealed the bottles, and repackaged them for distribution with an erroneous expiration date. *Ibid.*

The government's evidence also established that an Alra worker dropped a metal pipe into a mixer containing a large batch of K+10. The pipe was then ground up into tiny pieces. After unsuccessfully attempting to remove the metal pieces, petitioners tableted the drug and released it for sale. Gov't C.A. Br. 8-9.

The government's evidence further showed that Alra received 36 drums of concentrated Lactulose that were dented, punctured, and leaking. Under Bhutani's directions, workers injected glue into the leaks and covered the leaks with duct tape. Although Bhutani told an insurance adjuster that the Lactulose concentrate was not fit for human consumption and would have to be destroyed, petitioners used the concentrate as a drug component and sold the contaminated drugs to the public. Gov't C.A. Br. 9.

3. After petitioners were convicted for their conduct, petitioners moved for a new trial, based on new evidence that Lactulose was effective with a pH as low as 2.5. Pet. App. 26. Petitioners asserted that the new evidence undermined the government's assertion that petitioners had a motive to spike the Lactulose, and that the spiking counts had a spillover effect on the other counts. The district court granted petitioners' motion. *Id.* at 36-66.

The court of appeals reversed. Pet. App. 22-35. The court first held that the government's failure to disclose the pH evidence did not violate *Brady* v. *Maryland*, 373 U.S. 83 (1963), because it did not come into the government's possession "until well after the trial had ended." Pet. App. 29. The court further held that the new evidence did not undermine the government's argument that petitioners had a motive to spike the Lactuolose. The court explained that the government never

claimed that petitioners spiked the Lactolose to mask the fact that the drug would soon become ineffective. *Id.* at 31. Instead, the government argued that petitioners spiked the Lactulose because the lots were old and petitioners wanted to conceal the age of the lots—an argument that was not undercut by evidence that the Lactulose was not close to becoming ineffective at the time it was spiked. *Ibid.* Finally, the court ruled that the new evidence had no bearing on petitioners' convictions on the counts that did not relate to the spiking of the Lactulose. *Id.* at 34.

4. On remand, petitioners once again moved for a new trial, claiming that the government's position on appeal contradicted its theory at trial. The district court denied the motion, holding that the court of appeals had already concluded that there was no inconsistency. Pet. App. 18-19. The district court also rejected petitioners' contention that the jury instructions were defective because they failed to require the jury to find materiality as an element of an FDCA violation. *Id.* at 19.

The court of appeals affirmed. Pet. App. 1-15. The court first rejected petitioners' contention that the government's position on appeal contradicted its trial theory. The court explained that "[a] second read of the trial transcripts reveals that the government's position at trial and on appeal has been consistent." *Id.* at 2. In particular, "[t]he government did not show at trial that the [old] Lactulose was outside the accepted pH range or medically ineffective; rather it admitted that the pH was at all times within range, but that it was dropping, which signaled degradation, and in order to mask any degradation the defendants raised the pH by adding sodium hydroxide so that the fact that it was being sold

past its expiration date could not be detected." *Id.* at 2-3.

The court of appeals also rejected petitioners' contention that, because of a drafting error during a 1984 recodification, it was not a crime under 21 U.S.C. 331(e) for petitioners to alter their records with the intent to defraud or mislead. The court held that Congress clearly intended to make the alteration of records with the intent to mislead a felony. Pet. App. 6-10. The court emphasized that "in strictly construing a [criminal] statute, courts ought not deprive it of the obvious meaning intended by Congress, nor abandon common sense." *Id.* at 7.

The court of appeals also affirmed the district court's sentencing rulings. It held that the district court correctly applied the Sentencing Guideline applicable to offenses involving fraud or deceit. Pet. App. 10-11. The court further held that the district court correctly assessed the amount of the loss attributable to petitioners' deceit on the basis of petitioners' gain from selling the adulterated drugs. *Id.* at 11-14.

ARGUMENT

1. Petitioners contend (Pet. 17-20) that, under *Neder* v. *United States*, 527 U.S. 1 (1999), the jury was required to find materiality as an element of the offenses under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.* That contention does not warrant review. The court of appeals did not address whether *Neder* requires a materiality finding for convictions under the FDCA. Nor was the resolution of that issue necessary in order to affirm petitioners' FDCA convictions. The jury was instructed to find materiality on the violation on which petitioners sought a materiality instruction, and the failure to give such an

instruction on the other FDCA counts did not constitute plain error.

Petitioners requested a materiality instruction relating to their failure to maintain accurate records. Pet. 19. Although the district court did not give the instruction that petitioners requested, it did instruct the jury that it was required to find materiality. In particular, the court instructed the jury that, in order to find petitioners guilty of failing to maintain accurate records, it was required to find that petitioners "*materially* altered the manufacturing procedures for [Lactulose] by causing sodium hydroxide to be added to this product more than two years after its original manufacture," and in concealing "this unauthorized procedure from the FDA, intentionally failed to document this unproved manufacturing procedure in the production batch records." Tr. 5842-5843 (emphasis added). Assuming that *Neder* requires a materiality instruction, the district court's instruction fulfilled that requirement.

Petitioners did not request a materiality instruction relating to any other FDCA violation. Thus, petitioners' contention that the district court erred in failing to give a materiality instruction on the other FDCA counts is subject to review only for plain error. See Fed. R. Crim. P. 52(b); *Johnson* v. *United States*, 520 U.S. 461 (1997). Under the plain error standard, petitioners must show not only that the court erred in failing to give a materiality instruction. They must also show that (1) the error is "plain" or "obvious," (2) the error "affect[ed] substantial rights" and (3) the error "seriously affect[ed] the fairness, integrity, or public reputation of judicial proceedings." *Johnson*, 520 U.S. at 467-468.

Even assuming that the district court erred in failing to give a materiality instruction on the other FDCA counts, that error was not plain or obvious under *Neder*. In *Neder*, the Court held that the mail fraud, bank fraud, and wire fraud statutes require proof of materiality. The Court reasoned that when Congress criminalizes "fraud," it intends to incorporate fraud's common law materiality requirement unless the statutory context dictates otherwise. 527 U.S. at 23. The FDCA, however, criminalizes violations of the Act that are committed with "the intent to defraud *or mislead*." 21 U.S.C. 333(a)(2) (emphasis added). *Neder* does not address whether such a statute incorporates a materiality requirement. *Neder* therefore does not make it "clear" or "obvious" that the FDCA requires proof of materiality.

Petitioners also cannot establish the other two components of plain error. Count 3 charged petitioners with adulterating the drug Lactulose by adding sodium hydroxide, and Count 6 charged petitioners with distributing the adulterated Lactulose. The jury's finding of guilt with respect to record-keeping, on which a materiality instruction was requested and given, necessarily incorporated a finding that the addition of the sodium hydroxide was a material change. Moreover, petitioners did not contend at trial that adding sodium hydroxide would be insignificant or unimportant; they contended that the conduct did not happen. Tr. 5004, 5254, 5395. Petitioner's own expert witness, Dr. Robyt, made clear that adding sodium hydroxide to Lactulose would be highly material. He testified that sodium hydroxide injected into bottles of Lactulose would be potentially lethal. Tr. 4328, 4334. He further testified that if the sodium hydroxide got into the intestines it could make the patient very sick. Tr. 4338. In those

circumstances, the district court's failure to give a materiality instruction on Counts 3 and 6 neither affected petitioners' substantial rights nor seriously affected the fairness, integrity, or public reputation of judicial proceedings.

Counts 7 and 8 charged that petitioners used contaminated Lactulose concentrate from dented and leaking drums as a drug ingredient and then sold the contaminated drug. The evidence that established that petitioners engaged in that conduct also established its materiality. Specifically, the evidence showed Alra received 36 drums of concentrated Lactulose that were leaking, that under Bhutani's directions, workers injected glue into the leaks and covered the leaks with duct tape, and that Bhutani admitted that the Lactulose concentrate was not fit for human consumption. Gov't C.A. Br. 9. A jury that credited that evidence could not have rationally concluded that petitioners' deception in relation to that conduct was immaterial. Accordingly, the failure to give a materiality instruction on those counts neither affected petitioners' substantial rights nor seriously affected the fairness, integrity, or public reputation of judicial proceedings. Count 10 charged that petitioners distributed K+10 that had been contaminated when a steel pipe was dropped into a blender and ground up into the product during the manufacturing process. Petitioners did not contend that the shipment of drug tablets that were contaminated by metal shards would be insignificant. Rather, they claimed that they destroyed the contaminated portion of the K+10 batch. Govt' C.A. Br. 8-9. The jury, however, rejected petitioners' version of the events, and found that petitioners sold tablets that were contaminated by metal shards. Because a deception relating to selling drugs contaminated with metal shards is obviously

material, the failure to give a materiality instruction on Count 10 neither affected petitioners' substantial rights, nor seriously affected the fairness, integrity, or public reputation of judicial proceedings.

Petitioners were also convicted of conspiring to commit the offenses discussed above. For the same reasons that the failure to give a materiality instruction did not constitute plain error on the substantive counts, it did not constitute plain error on the conspiracy count.

Petitioners contend (Pet. 18-19) that the decision below conflicts with the Ninth Circuit's holding in *United States* v. *Watkins*, 278 F.3d 961 (2002), that the FDCA requires proof of materiality. Because the court of appeals in this case did not address whether the FDCA requires proof of materiality, and because petitioners' FDCA convictions must be affirmed even if the FDCA requires proof of materiality, however, there is no conflict between the decision below and *Watkins*.

2. Petitioners also contend (Pet. 21-23) that review is warranted to decide whether Section 331(e) prohibited the failure to maintain accurate records when their charged conduct occurred. That question does not warrant review. In 1990, Congress clarified that Section 331(e) prohibits the failure to maintain records. See Vaccine and Immunization Amendments of 1990, Pub. L. No. 101-502, § 5(j), 104 Stat. 1289. Petitioners' contention that Section 331(e) did not cover such conduct when their charged conduct occurred therefore does not raise any issue of prospective importance. In addition, under the Sentencing Guidelines, petitioners' convictions for failing to maintain records did not add to the offense level that was produced by their convictions for adulterating the Lacutalose and distributing the adulterated product. A reversal of petitioners' conviction on the failure to maintain records count there-

fore would not have any practical impact on petitioners' sentences.

In any event, the court of appeals correctly held that petitioners' failure to maintain accurate records violated Section 331(e). In 1962, Congress amended the FDCA to require that drug manufacturers provide the FDA with information concerning drugs that the agency had previously approved for sale. That amendment added a new subsection to the FDCA, designated as 21 U.S.C. 355(j) (1994 & Supp. V 1999), which provided in pertinent part:

> (1) In the case of any drug for which an approval of [a new drug application] is in effect, the applicant shall * * * make such reports to the Secretary, of data relating to * * * information * * * with respect to such drug, as the Secretary may by general regulation * * * prescribe.

Drug Amendments of 1962, Pub. L. No. 87-781, § 103, 76 Stat. 782. The same 1962 legislation also amended 21 U.S.C. 331(e) to prohibit any failure to establish or maintain records required by 21 U.S.C. 355(j) (1994 & Supp. V 1999).

The FDCA then remained unchanged for 22 years. In 1984, Congress amended the FDCA to provide for new procedures relating to generic drugs. A new generic drug subsection was designated as Section 355(j), while the previous Section 355(j)—the record-keeping provision—was redesignated as Section 355(k). Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585.

Congress neglected in its 1984 legislation to amend 21 U.S.C. 331(e) to reflect that what had previously been Section 355(j) was now Section 355(k). Section 331(e) therefore continued to prohibit "the failure to

establish or maintain any record * * * required under [21 U.S.C. 355(j)]," even though the new Section 355(j), relating to generic drug approvals, did not include record-keeping and reporting requirements. In 1990, Congress enacted a clarifying amendment to Section 331(e) that struck the reference to Section 355(j) and substituted a reference to Section 355(k). § 5(j), 104 Stat. 1289.

Because petitioners' charged conduct occurred after the 1984 amendments, but before the 1990 clarifying amendment, the relevant question is whether Section 331(e) prohibited the failure to maintain records during that period. In resolving that question, the court of appeals either had to interpret the lingering reference to Section 355(j) as a reference to the redesignated Section 355(k), or it had to give the prohibition in Section 331(e) against failing to establish or maintain required records no meaning at all. The court of appeals correctly chose the interpretation that gave continuing meaning to that prohibition, rather than the one that would have rendered it a nullity. Read in the manner suggested by petitioners, Congress's 1984 amendments to the FDCA repealed the 22-year-old sanction against failure by a drug manufacturer to prepare records that it was still required to maintain, and they did so while still leaving in place language in Section 331 that prohibited the failure to maintain required records. The court of appeals correctly rejected that result as inconsistent with Congress's clear intent and common sense.

This Court and numerous courts of appeals have interpreted criminal laws to prohibit conduct that Congress clearly intended to prohibit notwithstanding the presence of inadvertent drafting errors that rendered the conduct outside the literal reach of the laws. See

United States v. *Lacher*, 134 U.S. 624, 625-632 (1890); *United States* v. *Graham*, 169 F.3d 787, 790-791 (3d Cir.), cert. denied, 528 U.S. 845 (1999); *United States* v. *Warren*, 149 F.3d 825, 827-828 (8th Cir. 1998); *United States* v. *Rossetti Bros., Inc.*, 671 F.2d 718, 720 (2d Cir. 1982); *United States* v. *Scrimgeour*, 636 F.2d 1019, 1021-1024 (5th Cir. Unit B), cert. denied, 454 U.S. 878 (1981); *United States* v. *Moore*, 613 F.2d 1029, 1039-1045 (D.C. Cir. 1979), cert. denied, 446 U.S. 954 (1980); *United States* v. *Babcock*, 530 F.2d 1051, 1053-1054 (D.C. Cir. 1976). The court of appeals' decision in this case is consistent with those decisions.

Petitioners contend (Pet. 21-22) that the decision below conflicts with the decisions in *United States* v. *Faygo Beverages, Inc.*, 733 F.2d 1168 (6th Cir. 1984), and *United States* v. *RSR Corp.*, 664 F.2d 1249, 1253 (5th Cir. Unit A), cert. denied, 459 U.S. 1016 (1982). Neither of those decisions, however, involved an interpretation of Section 331(e). Instead, they involved a construction of two provisions of the Interstate Commerce Act that have since been amended. While there is some tension between the general approach to statutory interpretation adopted by those older decisions and the approach adopted by the court below, that tension is not a sufficient basis for granting review in this case. Should any tension in general approach lead to conflicting interpretations of the same statute, review by this Court might then be warranted. Because there is no conflict in the circuits concerning the correct interpretation of Section 331(e), because the issue arising under Section 331(e) has no prospective importance, and because a reversal of petitioners' conviction on that count would not affect their sentences, review in this case is unwarranted.

3. Petitioners contend (Pet. 22-23) that the district court erred in applying Guidelines § 2F1.1, the fraud Guideline, rather than Guidelines § 2N2.1(b), the drug regulation Guideline. Guidelines § 2N2.1(b), however, expressly states that "[i]f the offense involved fraud, apply § 2F1.1." Since petitioners' conduct involved fraud, the district court correctly applied Guidelines Section 2F1.1.

Nor did the application of Section 2F1.1 violate the Ex Post Facto Clause. As petitioners note, the Sentencing Commission did not adopt the cross-reference in Section 2N2.1(b) until 1992, after their charged conduct occurred. But the Guidelines in effect at the time of petitioners' criminal conduct also required the application of Guidelines § 2F1.1 to fraudulent conduct. At that time, the commentary to Section 2N2.1 specified that "[i]f the offense involved theft, fraud, bribery, revealing trade secrets, or destruction of property, apply the guideline applicable to the underlying conduct, rather than this guideline." Guidelines § 2N2.1, comment. (n.2) (1988) (emphasis added). That Commentary reflected a binding interpretation of the Guidelines. *Stinson* v. *United States*, 508 U.S. 36, 43 (1993). Thus, even before the Commission adopted the 1992 cross-reference, the courts of appeals uniformly applied Section 2F1.1 to FDCA cases involving the intent to defraud or mislead. *United States* v. *Cambra*, 933 F.2d 752 (9th Cir. 1991); *United States* v. *Anderson*, 45 F.3d 217, 220 (7th Cir. 1995); *United States* v. *Arlen*, 947 F.2d 139, 146 (5th Cir. 1991), cert. denied, 503 U.S. 939 (1992). Because the Guidelines required application of Section 2F1.1 to FDCA cases involving fraud both at the time of petitioners' criminal conduct and at the time of petitioners' sentencing, the district court's use of that

Guideline did not violate the Ex Post Facto Clause. *Johnson* v. *United States*, 529 U.S. 694, 699 (2000).

4. Petitioners contend (Pet. 23-24) that there was insufficient evidence to support the jury's finding that the Lactulose they sold from the leaking drums was contaminated. Specifically, petitioners argue that the jury was required to defer to their expert witness who testified that microrganisms would not have entered the leaking drums. That contention is without merit. On cross-examination, the government established that the witness' opinion was both incomplete and based on limited information. For example, the defense witness admitted that he did not test for mold, dirt, glue residue, or other possible contaminants. Gov't C.A Br. 9. The jury also heard ample evidence that the Lactulose from the leading drums was contaminated. In particular, petitioner Bhutani told an insurance adjuster that the Lactulose concentrate was not fit for human consumption. Gov't C.A. Br. 9. In those circumstances, the court of appeals correctly declined petitioners' "invitation to reweigh the evidence." Pet. App. 15.

5. Petitioners contend (Pet. 25-26) that the district court erred in determining that there was a loss attributable to their fraud under Guidelines § 2F1.1. That contention is without merit and does not warrant review. The district court correctly ruled that, because petitioners' customers did not receive the drugs for which they had bargained, the amount they paid for the drugs should be considered the amount of their loss. The court then adopted a very conservative estimate of that loss—$200,000. Gov't C.A. Br. 44.

The district court's approach is fully consistent with decisions of other courts of appeals construing the fraud Guideline. See *United States* v. *Marcus*, 82 F.3d 606 (4th Cir. 1996); *United States* v. *Gonzalez-Alvarez*, 277

F.3d 73, 78 (1st Cir. 2002). The courts recognize that economic gain, as measured by gross sales, is an appropriate measure of loss when, as here, there is actual, probable, or intended loss to consumers. In the context of adulterated prescription drug sales, economic gain to the manufacturer is the proper measure of loss when drugs do not meet FDA specifications and are thus of unknown value. *Marcus*, 82 F.3d at 608 (a change in formula "rendered the [drug] something other than what it purported to be because the altered formula had not been approved by the FDA and was of unknown safety and efficacy"); *id.* at 610 ("as such, consumers did not receive that for which they bargained—an FDA-approved drug of *known* safety and efficiency").

Petitioners err in asserting (Pet. 25) that the Seventh Circuit's ruling on that point conflicts with the Fourth Circuit's ruling in *United States* v. *Chatterji*, 46 F.3d 1336 (4th Cir. 1995). In *Chatterji*, the Fourth Circuit held that customer loss should not be used where the efficiency and safety of the drug is not implicated by the defendant's conduct. In *Marcus*, the Fourth Circuit subsequently clarified that *Chatterji* does not apply where, as here, the adulteration of the drug implicates the safety and efficiency of the product. The court of appeals here expressly followed the rationale of *Marcus*. Pet. App. 12-14. Thus, there is no conflict on that issue between the Seventh and Fourth Circuits. In any event, any conflict in interpretation of the Guidelines is appropriately resolved by the Sentencing Commission. *Braxton* v. *United States*, 500 U.S. 344, 347-348 (1991).

6. Finally, petitioners contend (Pet. 26-30) that they should have obtained a new trial because the government presented a different theory on appeal than the one it presented to the jury. In petitioners' view, the

government's theory at trial was that the Lactulose was medically ineffective or would soon become medically ineffective, and that petitioners' spiked the Lactulose to mask that fact, while the government's theory on appeal was that petitioners' spiked the Lactulose in order to mask its age. After "[a] second read of the trial transcript," however, the court of appeals determined that "the government's position at trial and on appeal has been consistent." Pet. App. 2. In particular, the court found that "[t]he government did not show at trial that the [old] Lactulose was outside the accepted pH range or medically ineffective; rather it admitted that the pH was at all times within range, but that it was dropping, which signaled degradation." *Id.* at 2-3. The court further determined that the government's theory at both stages was that, "in order to mask any degradation the defendants raised the pH by adding sodium hydroxide so that the fact that it was being sold past its expiration date could not be detected." *Id.* at 3. None of the excerpts from the trial cited by petitioners (Pet. 27-30) undermines the court of appeals' determination. In any event, that fact-bound issue does not warrant review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

THEODORE B. OLSON
Solicitor General

ROBERT D. MCCALLUM, JR.
Assistant Attorney General

DOUGLAS N. LETTER
ROBERT M. LOEB
LAWRENCE G. MCDADE
Attorneys

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